

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA, *ex rel.*  
DILBAGH SINGH, M.D., *et al.*,

Plaintiffs,

V.

BRADFORD REGIONAL MEDICAL CENTER,  
*et al.*,

Defendants.

CIVIL ACTION NO. 04-186-E

JUDGE COHILL

**BRIEF IN SUPPORT OF RELATORS’  
MOTION FOR SUMMARY JUDGMENT**

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**BRIEF IN SUPPORT OF RELATORS'**  
**MOTION FOR SUMMARY JUDGMENT**

As discussed below, the undisputed evidence establishes that Defendant Bradford Regional Medical Center (“BRMC” or the “hospital”) submitted thousands of false claims for payment to the Medicare program arising out of referrals from Drs. Peter Vaccaro and Kamran Saleh. These claims were false because BRMC had a non-exempt financial relationship with Drs. Vaccaro and Saleh and their medical practice, V&S Medical Associates, LLC (“V&S”), as set forth in the Stark statute, rendering it ineligible to submit claims to Medicare based on such referrals. These claims were also false because they were submitted in violation of the Anti-Kickback Statute, which prohibits the payment or receipt of remuneration in order to induce referrals paid for by a federal healthcare program. The claims at issue were submitted to Medicare by BRMC, and were caused to be submitted by V&S and Drs. Vaccaro and Saleh. Accordingly, the Court should grant summary judgment in favor of the United States, holding that Defendants are liable under the False Claims Act.

**I. STATEMENT OF FACTS**

**A. V&S acquires the GE nuclear camera.**

Drs. Peter Vaccaro and Kamran Saleh are the owners of V&S Medical Associates, LLC, a medical practice located in Bradford, Pennsylvania. Saleh Dep., p. 6, 9-10 (Apx., Doc. 3).<sup>1</sup> Drs. Vaccaro and Saleh both practice internal medicine. *Id.*, p. 9-10; Vaccaro Dep., p. 7-8 (Apx., Docs. 3, 4). Prior to 2001, they were a significant source of referrals to BRMC, both for inpatient admissions and for outpatient procedures, including diagnostic tests performed on a nuclear imaging

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<sup>1</sup> “Apx.” refers to the Appendix in Support of Relators’ Motion for Summary Judgment, filed contemporaneously herewith.



camera located at BRMC. Vaccaro Dep., p. 18-20, 24; Saleh Dep., p. 17-22; BRMC 30(b)(6) Dep., p. 97, 129, 175; Leonhardt Dep., p. 18 (Apx., Docs. 3, 4, 2, 1).

In 2001, however, V&S began to consider obtaining its own nuclear camera and installing it in its office. This would allow V&S to perform nuclear imaging tests in-house, rather than referring such tests to BRMC. Upon learning of V&S's plans, BRMC's CEO, George Leonhardt, became concerned about the effect that would have on the hospital. In March 2001, Leonhardt asked BRMC's senior vice president of operations, Glen Washington, for information about Vaccaro and Saleh's nuclear medicine referrals, in order to determine "what kind of impact could that have on us." Leonhardt Dep., p. 94-95; BRMC 30(b)(6) Dep., p. 67 (Apx., Docs. 1, 2). Washington informed Leonhardt that annual gross nuclear medicine revenues were approximately \$2,798,578, of which approximately \$2,274,094 were outpatient revenues. Leonhardt Dep., Exhibit 10 (at HOSP0004401) (Apx., Doc. 13). Washington told Leonhardt that Drs. Vaccaro, Saleh, and Jamil (another physician who rented space in V&S's office) ordered 42.5% of the hospital's nuclear studies, and that V&S had enough nuclear medicine patients to support their own machine. *Id.* (at HOSP0004402) ("They have enough to pay for a machine. A rule of thumb is they need to be able to do 3 per day."); *see also* Saleh Dep., p. 7-8 (Apx., Doc. 3).

Because Drs. Vaccaro and Saleh were a major referral source to the hospital, Leonhardt became concerned that their acquisition of a nuclear camera would have a "very detrimental impact" on the hospital, including on its ability to hire a full-time cardiologist and start a cardiology practice. BRMC 30(b)(6) Dep., p. 94, 97 (Apx., Doc. 2). Nuclear imaging referrals were significant because, as Leonhardt acknowledged, "nuclear cardiology is a key portion of any diagnostic cardiology service." Leonhardt Dep., p. 6 (Apx., Doc. 1). Indeed, nuclear imaging tests were the most profitable part of a cardiology practice. BRMC 30(b)(6) Dep., p. 116-17 (Apx., Doc. 2). Moreover, as Leonhardt testified, the loss of nuclear imaging referrals would also lead to the loss

of revenue from follow-up tests:

They are generally, depending on what the result of the nuclear test is, there are follow-up tests. If the nuclear test is being done elsewhere, being read by somebody else, those follow-up tests tend to go along their referral patterns, not the traditional ones.

BRMC 30(b)(6) Dep., p. 121-22; *id.*, p. 122 (noting that “[o]ther diagnostics, after nuclear medicine ... [are] the cardiac cath, the referral for cardiac rehab, those kind of things.”); *see also* Leonhardt Dep., p. 5-6 (noting loss of revenue from follow-up tests) (Apx., Docs. 2, 1).

If physicians such as V&S performed nuclear imaging procedures in-house rather than referring them to the hospital, Leonhardt testified, a cardiologist might believe that the hospital would not have enough business to support his practice:

Q. Why did you believe that it would be more difficult to hire a full-time cardiologist if V&S had their nuclear camera?

A. If we’re trying to convince a full-time cardiologist to come to that community, that individual is going to have a series of questions, you know, can you support the practice, where are the patients going to come from, are the physicians in the community going to support the development of this practice; and to the extent that a key practice has a financial reason not to support the development of that service, that’s going to make it more difficult.

Leonhardt Dep., p. 10; *see also id.*, p. 6; BRMC 30(b)(6) Dep., p. 105 (ability to attract cardiologist would be “diminished considerably if a key cardiac diagnostic service was going to be developed in the offices of internists and, therefore, would not be available to support that cardiologist”) (Apx., Docs. 1, 2). Leonhardt noted that V&S was a large enough referral source that the loss of their referrals alone was a significant impediment to establishing a cardiology practice. Leonhardt Dep., p. 14; *see also* BRMC 30(b)(6) Dep., p. 97 (noting that Drs. Vaccaro and Saleh “had a substantial part of the patient population as their clients or patients”); *id.* p. 105 (“I thought the impact would be significantly detrimental”) (Apx., Docs. 1, 2).

On April 3, 2001, Mr. Leonhardt met with Drs. Saleh and Vaccaro and explained that their acquisition of a nuclear camera would negatively impact the hospital’s financial position and affect

the recruitment of a cardiologist. Saleh Dep., p. 38-40, 61 and Exhibit 4 (Apx., Docs. 3, 18).

Between April 3 and June 1, 2001, Mr. Leonhardt met with Drs. Vaccaro and Saleh on several more occasions. Saleh Dep., p. 62 and Exhibit 4 (Apx., Docs. 3, 18). In a subsequent letter, Mr. Leonhardt noted that the parties discussed the possibility of entering into a joint venture “within the Safe Harbor exceptions to Stark II.” Saleh Dep., p. 62 and Exhibit 4 (Apx., Docs. 3, 18). However, despite these discussions, Vaccaro and Saleh decided to go ahead with their plans. Saleh Dep., p. 38-40 (Apx., Doc. 3).

In May 2001, after Mr. Leonhardt had met with Drs. Vaccaro and Saleh about their nuclear camera plans, BRMC adopted a Policy on Physicians with Competing Financial Interests. BRMC 30(b)(6) Dep., p. 83 (Apx., Doc. 2). The policy provided that, if a physician had a financial relationship with a competing health care entity that may have a significant impact upon the hospital, that physician would be ineligible for hospital privileges. BRMC 30(b)(6) Dep., p. 86-87 (Apx., Doc. 2).

In June 2001, V&S entered into a 63-month lease with General Electric (“GE”) for a nuclear camera. Saleh Dep., p. 164-65 and Ex. 33 (Apx., Docs. 3, 38). Drs. Vaccaro and Saleh guaranteed V&S’s obligations to GE. (Apx., Doc. 50, at V&S00375-00378, V&S00383, V&S02267-02270, V&S00681-00684). After the GE camera was placed in V&S’s office, their referral practices changed with respect to nuclear imaging. Rather than referring patients to BRMC for nuclear imaging tests as they had done previously, Drs. Vaccaro and Saleh began to perform such tests in their own office, thus decreasing their nuclear referrals to BRMC. Saleh Dep., p. 37 and Ex. 8 (letter from hospital stating that “Data collected by the Medical Center shows that you have significantly changed your practice pattern in terms of your usage of the Medical Center’s equipment. We understand that is because you are now using the V&S equipment in its place.”); Vaccaro Dep., p. 25; BRMC 30(b)(6) Dep., p. 128 (agreeing that V&S’s imaging was having a

negative impact on the hospital); Leonhardt Dep., p. 6-7 (Apx., Docs. 3, 21, 4, 2, 1). However, their referral practices with respect to inpatient admissions and other outpatient procedures remained the same. Saleh Dep., p. 37 (Apx., Doc. 3). Thus, the only referrals BRMC lost as a result of V&S obtaining their own nuclear camera were V&S's referrals for nuclear imaging tests. However, BRMC was concerned that V&S might reduce its other inpatient and outpatient referrals to the hospital. Among other things, although V&S did not currently offer CT scans or MRIs in their office, BRMC was concerned that they might begin to do so, thus reducing their referrals to the hospital for such procedures. Leonhardt Dep., p. 57-58 and Exhibit 4 (at HOSP0007444); BRMC Dep., p. 160-62 and Exhibit 14 (at HOSP0007444) (Apx., Docs. 2, 7).

**B. BRMC threatens to revoke Vaccaro and Saleh's privileges.**

After adopting the policy against competing interests, BRMC began putting pressure on V&S to get out of the nuclear imaging business by threatening to revoke their privileges. Mr. Leonhardt told Drs. Vaccaro and Saleh that they were subject to the policy and faced the possibility of losing their hospital privileges if they continued competing against the hospital. Leonhardt Dep., p. 19; Saleh Dep., p. 43-45; Vaccaro Dep., p. 42 (Apx., Docs. 1, 3, 4). Through their attorneys, Drs. Vaccaro and Saleh objected to BRMC's pressure, claiming that the hospital was illegally seeking to extract referrals from V&S, in violation of the Stark and Anti-Kickback statutes. On January 22, 2002, attorney Marc Raspanti sent a letter to George Leonhardt, stating that the hospital's actions "violate federal law, in particular, the federal anti-kickback criminal statute." Saleh Dep., Ex. 5, at V&S00124 (Apx., Doc. 19). This letter also noted that the Stark statute and the False Claims Act provide civil penalties "for those who enter into arrangements which compensate based upon referrals." *Id.*, at V&S00125 (Apx., Doc. 19). The letter asserted that "The Medical Center is conditioning privileges on referrals streams. This is precisely the type of arrangement that the anti-kickback laws were intended to prevent." *Id.* (Apx., Doc. 19).

On February 15, 2002, Mr. Raspanti sent another letter to Mr. Leonhardt, noting that “the anti-kickback laws are violated even where only ‘one purpose’ of a payment or exchange is to induce referrals.” Saleh Dep., Ex. 7, at V&S00155; Leonhardt Dep., p. 76-77 and Ex. 6 (Apx., Doc. 20). Mr. Raspanti also noted that, since July 2001, Drs. Vaccaro and Saleh had been subject to numerous case reviews, and that “[s]uch harassment of physicians who are perceived as having a financial conflict of interest is an absolute abuse of the peer review process.” *Id.* at V&S00159 (Apx., Doc. 20). Mr. Raspanti bluntly stated that “We know of no case that more clearly establishes a hospital’s attempt to extract an exclusive referral stream from a physician.” *Id.*; Leonhardt Dep., p. 21-22, 76-77 and Ex. 6 (Apx., Docs. 20, 1).

On June 11, 2002, Mr. Leonhardt sent a letter to Drs. Vaccaro and Saleh notifying them that the board had preliminarily determined they were in violation of the policy against competing interests. Having raised the stick, the letter then proceeded to offer a carrot, stating that the parties should meet to discuss “[w]hether there is interest ... in working together in regard to the equipment and services in question, be it through a joint venture or other appropriate means.” Saleh Dep., Ex. 9 (Apx., Doc. 22). In a June 26, 2002 letter, Leonhardt proposed that the parties enter into an “under arrangements” venture, under which physicians on the hospital medical staff would form a physician-owned diagnostic center to provide diagnostic tests. This diagnostic center would enter into a contract with BRMC, whereby the center would be paid a fixed amount for each test furnished to hospital patients. The hospital, not the diagnostic center, would then bill the patient or third-party payors for the service. Saleh Dep., Ex. 4, 11; BRMC 30(b)(6) Dep., Ex. 11 (Apx., Docs. 18, 23). This proposed “under arrangements” venture would not simply provide nuclear imaging tests, but would also provide other diagnostic procedures such as CTs and MRIs, which were not then being provided by V&S. Leonhardt Dep., p. 72-73; BRMC 30(b)(6) Dep., p. 161; Saleh Dep., p. 35-36 (Apx., Docs. 1, 2, 3). In his letters to Vaccaro and Saleh, Leonhardt stressed the need to structure

the venture in such a way that it satisfied the Stark statute. Saleh Dep., Ex. 4, 11; BRMC 30(b)(6) Dep., Ex. 11 (Apx., Docs. 18, 23).

Over the next year or so, the parties had numerous discussions regarding the possibility of an under arrangements venture, without success. Even as it was negotiating with the hospital, V&S continued to contend that the hospital was illegally using the privileging issue in an effort to gain referrals. In a January 17, 2003 letter to BRMC's counsel, V&S's attorney, Marc Raspanti, complained that the hospital was attempting to blackmail them into entering into a poor business deal by the threat of revoking privileges:

In [a January 10, 2003] letter, the Medical Center directly threatens to revoke the medical staff privileges of Drs. Saleh and Vaccaro based upon their refusal to be coerced into a poor medical, and even worse business, decision.... The Medical Center's conduct is shocking, disappointing and, quite frankly, economic blackmail.

Saleh Dep., Ex. 15, at V&S 00560, 00561 (Apx., Doc. 26). Mr. Raspanti asked for "[a]ll opinions concerning the legality of the nuclear camera venture" contemplated by BRMC, stating that "I am sure that we can all agree that neither party wishes to become involved in a business venture which is in violation of federal or state law." *Id.* at V&S00562.

In a February 5, 2003 letter, another of V&S's attorneys, Edward Kabala, continued to express concerns about the legality of any arrangement, and insisted that the parties obtain an advisory opinion from the Office of Inspector General:

While the "under arrangements" process may be entirely legal, we would want to be sure that we will get an unconditional opinion or an advisory opinion from the Office of the Inspector General, to the effect that the final arrangement and the process that led to it would not be deemed inappropriate.

Saleh Dep., Ex. 16, at V&S 01642; Kabala Dep., Ex. 3 (Apx., Doc. 27). As George Leonhardt acknowledged, it was considered essential that an OIG advisory opinion about the legality of the venture be obtained before entering into any under arrangements venture. BRMC 30(b)(6) Dep., p. 138; *see also* Saleh Dep., p. 101. (Apx., Doc. 2, 3).

**C. The parties consider a possible sublease arrangement.**

At some point in early 2003, as the discussions over the under arrangement venture bogged down, the parties began discussing an alternative resolution, under which BRMC would agree to sublease the nuclear camera from V&S. BRMC 30(b)(6) Dep., p. 126-27, 139, 151 and Ex. 15; Saleh Dep., p. 116-18 and Ex. 21 (Apx., Docs. 2, 28, 3, 29). In a February 11, 2003 letter proposing a sublease arrangement, V&S's attorney assured BRMC that "[m]y clients have indicated that all of their Nuclear Medicine Studies can be accommodated by a combination of their current camera and those at BRMC." Leonhardt Dep., p. 37 and Exhibit 2 (at V&S 01629) (Apx., Docs. 1, 40). On April 16, 2003, the parties entered into a preliminary agreement, or an "agreement to agree," providing that the parties would enter into a sublease for the nuclear camera, while continuing efforts to develop an under arrangements venture. Saleh Dep., p. 160-62 and Ex. 31 (Apx., Docs. 3, 37).

Before entering into a final sublease, BRMC had a "fair market value" assessment prepared by an accountant, Charles Day. The purported purpose of this report was to determine whether BRMC was paying fair market value under the proposed sublease arrangement, and George Leonhardt testified that he considered and relied on this report before executing the Equipment Sublease. BRMC 30(b)(6) Dep., p. 147-48; Leonhardt Dep., p. 54-56 (Apx., Docs. 2, 1). In performing his fair market value analysis, Mr. Day compared the revenues BRMC expected to generate with the sublease in place to the revenues it expected to receive without the sublease in place. The revenues in question consisted of referrals from V&S, and the projections were based on the expectation that V&S would refer such business to the hospital if the sublease arrangement were approved. Leonhardt Dep., p. 55-56 and Exhibit 4, p. 17 (Apx., Docs. 1, 7). Thus, BRMC's fair market value analysis was a straightforward projection of anticipated referrals from V&S.

George Leonhardt testified that he had to obtain board approval to enter into the sublease arrangement. Leonhardt Dep., p. 65-66 (Apx., Doc. 1). He prepared a summary of the sublease arrangement to present to the board. *Id.*, p. 66-68 and Exhibit 5 (Apx., Docs. 1, 8). This summary indicated that BRMC expected to generate \$402,000 in profit from the additional nuclear imaging referrals expected to be made by V&S following execution of the sublease. Leonhardt Dep., p. 71-72 and Exhibit 5 (Apx., Docs. 1, 8). Leonhardt testified that he made a presentation to the board based on this summary and obtained formal approval for the sublease arrangement. *Id.*, p. 72 (Apx., Doc. 1).

**D. The parties execute the Equipment Sublease.**

On or about October 1, 2003, the parties entered into an Equipment Sublease, pursuant to which BRMC agreed to sublease the GE camera from V&S for a five-year period. Under the sublease agreement, BRMC agreed to make monthly payments to V&S in the amount of \$30,200. Of this amount, only \$6,545 was for the actual sublease of the nuclear camera, and reflected a “pass-through” payment of amounts due under V&S’s primary lease with GE.<sup>2</sup> The remaining \$23,655 – i.e., the overwhelming majority of the sublease payments – constituted payment for a purported “non-compete” agreement by V&S and Drs. Vaccaro and Saleh, prohibiting them from competing with BRMC in the nuclear imaging area, and providing certain rights of refusal with respect to other diagnostic procedures such as CTs and MRIs. BRMC Dep., p. 142-143, 183-185 and Exhibit 20 (at HOSP0007684) (Apx., Docs. 2, 12).

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<sup>2</sup> The sublease provided that the “pass-through” amount would be reduced to \$3,045 on October 1, 2006, although the non-compete payment would remain the same.



**E. BRMC did not want the GE camera, and intended to replace it immediately.**

BRMC acknowledges that the purpose of the sublease was not simply to acquire a piece of equipment, but that it also hoped to get V&S's referral business as a result. Indeed, although it entered into a five-year sublease of the GE camera, BRMC did not believe that the camera was suited to its long-term needs! BRMC's 30(b)(6) designee, Glen Washington, admitted that "[t]he GE camera was an older model with some limited technology," and that "we did not feel that it would meet our future needs." BRMC Dep., p. 74 (Apx., Doc. 2). Mr. Washington testified that "[w]e informed [V&S] that that would not meet our future needs, because of the older technology and because of its nuclear cardiology limitations." *Id.*, p. 76. George Leonhardt testified that, at the time he entered into the sublease, "[w]e were aware that this was not going to be the camera we ultimately wanted." Leonhardt Dep., p. 49 (Apx., Doc. 1). In fact, although it executed a five-year lease for the GE camera, BRMC knew that it would shortly replace the GE camera with a new Philips camera. Leonhardt Dep., p. 78 (Apx., Doc. 1) (noting that "we couldn't get the camera from Philips that we had wanted at the time that the lease was entered into. It took us longer to get that than we expected it to."). Moreover, although BRMC agreed to sublease the GE camera for five years, there were only about three years remaining on V&S's primary lease with GE – thus, BRMC agreed to sublease the camera for longer than BRMC was leasing it. BRMC 30(b)(6) Dep., p. 144 (Apx., Doc. 2).

George Leonhardt agreed that the sublease arrangement was a "fairly cumbersome way to go out and acquire a piece of equipment," stating "Yes, if that was the only thing we were trying to accomplish. Obviously, it wasn't the only thing we were trying to accomplish." BRMC 30(b)(6) Dep., p. 140 (Apx., Doc. 2). Mr. Leonhardt admitted that BRMC hoped and expected to get V&S's referral business as a result of the sublease. *Id.*, p. 146, 154-157; Leonhardt Dep., p. 57 (Apx., Docs. 2, 1).

**F. BRMC pays V&S extra to leave the GE camera at V&S's office, where it had always been.**

Although the sublease stated that the nuclear camera would be delivered to BRMC's hospital, BRMC did not, in fact, ever take possession of the camera. Rather, BRMC left the camera in V&S's offices. BRMC Dep., p. 74-75 (Apx., Doc. 2). Indeed, BRMC paid V&S \$2,500 per month in rent, as well as payments for secretarial and other administrative expenses (on top of the sublease payments), to keep the camera at V&S's office, where it had always been. Saleh Dep., p. 152-58 and Exhibit 30 (Apx., Docs. 3, 41). This rental arrangement, with its substantial additional compensation, was not set forth in any written agreement signed by the parties. Thus, BRMC agreed to pay approximately \$30,000 per month to get a piece of equipment it did not particularly want or need, and then paid an additional \$2,500+ per month to leave the equipment where it was already located.

In addition to these payments, BRMC essentially subcontracted with V&S to perform and bill for tests on the nuclear camera that was now "leased" to BRMC. V&S continued to perform tests on the machine for their own patients. When a test would be performed with the camera, V&S would handle the billing and collections on behalf of BRMC, and would be paid a billing fee equal to 10% of collections. Saleh Dep., p. 152-154 and Exhibit 30 (Apx., Docs. 3, 41). This arrangement, which established yet another revenue stream from BRMC to V&S, is not set forth in any written agreement signed by the parties. The practical effect of this arrangement – which left the camera in V&S's office, although now "leased" to BRMC – was that whenever V&S had to perform a nuclear imaging test for one of their patients, they would do so on BRMC's camera in their own office, thus resulting in a referral to BRMC. And the more tests they ordered, the more they would receive in billing fees.

**G. The parties enter into a convoluted transaction to acquire a Philips camera and buy out the GE lease.**

The GE camera was used in this fashion for four or five months, through about March 2004. Saleh Dep., p. 158; Leonhardt Dep., p. 78 (Apx., Doc. 3, 1). At around that time, BRMC, V&S, and Philips Medical Capital, LLC (“Philips”) entered into a bizarre, complicated, and largely undocumented transaction for a new Philips nuclear camera. V&S entered into a five-year lease with Philips for a nuclear camera, with a monthly rental fee of \$4,450.40 (adjusted periodically). Leonhardt Dep., p. 82-85 and Exhibit 7, at V&S01053 (Apx., Doc. 10). In addition, Philips paid approximately \$200,000 to GE as an early termination fee to buy out the GE lease. V&S agreed to repay this amount in 60 monthly installments of \$3,958.13 (adjusted periodically). Leonhardt Dep., p. 82-85 and Exhibit 7, at V&S01076 (Apx., Docs. 1, 10). BRMC executed a guaranty of V&S’s obligations to Philips. Leonhardt Dep., Exhibit 7, at V&S01061 (Apx., Doc. 10).

Although the lease agreement was between Philips and V&S, the Philips camera was not placed in V&S’s office, but was placed in the hospital. Saleh Dep., p. 52 (Apx., Doc. 3). BRMC and V&S did not, however, enter into a written sublease agreement with respect to the Philips camera. Leonhardt Dep., p. 89; Saleh Dep., p. 52-53, 164 (Apx., Docs. 1, 3). Although there is no written sublease, BRMC has reimbursed V&S on a monthly basis for its lease payments to Philips. Leonhardt Dep., p. 84-85 (Apx., Doc. 1). In addition, BRMC has reimbursed V&S on a monthly basis for its payments to Philips for the buyout of the GE lease, although this arrangement is not set forth in any written agreement. Leonhardt Dep., p. 81; *see also id.* at p. 88 (acknowledging that buyout fee “was a hefty price”) (Apx., Doc. 1). However, although BRMC is the ultimate source of such payments, it did not obtain ownership or possession of the GE camera upon the early buyout of the GE lease. Rather, V&S retained the camera, although it did not use the camera after March 2004. Leonhardt Dep., p. 80-81; Saleh Dep., p. 52 (Apx., Docs. 1, 3). In December 2006, shortly

before receiving Relator's first discovery requests in this lawsuit, V&S made a charitable donation of the GE camera to Hamot Medical Center. (Apx., Doc. 50, at V&S03319-20).<sup>3</sup> In other words, BRMC essentially agreed to pay for the early termination of the GE lease, so that V&S could donate the GE camera to one of BRMC's competitors.

To the present day, BRMC continues to make monthly payments to V&S for (i) the noncompete payments under the Equipment Sublease, (ii) the rental payments for the Philips camera, and (iii) the payments for the buyout of the GE lease. Leonhardt Dep., p. 85, 89. In addition, BRMC pays V&S \$2,299.14 for a Philips service agreement, although that is also not set forth in a written agreement with V&S. (Apx., Doc. 50, at HOSP0003717-3719). The payments for the Philips camera are scheduled to run through January 2010; the payments for the buyout of the GE camera are scheduled to run through December 2009; and the "noncompete" payments are scheduled to run through September 2008. *Id.*

## II. APPLICABLE LEGAL STANDARDS

### A. The False Claims Act.

"The False Claims Act is the government's primary litigative tool for the recovery of losses sustained as the result of fraud against the government." *Avco Corp. v. United States Dep't of Justice*, 884 F.2d 621, 622 (D.C. Cir. 1989). Among other things, the FCA imposes liability upon any person who knowingly (i) presents or causes to be presented a false or fraudulent claim for payment to the United States, or (ii) makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government. 31 U.S.C. §

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<sup>3</sup> Notably, although V&S made the donation shortly before receiving Relators' first discovery requests, it did not produce documents relating to the donation until May 2008, after the close of discovery.

3729(a)(1)-(2). The term “knowingly,” as used in the FCA, means that the person “(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.” 31 U.S.C. § 3729(b); *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 241 (3d Cir. 2004). “As Justice Holmes put it, ‘[m]en must turn square corners when they deal with the Government.’” *United States v. Rogan*, 517 F.3d 449, 452 (7th Cir. Ill. 2008), *quoting Rock Island, Arkansas & Louisiana R.R. v. United States*, 254 U.S. 141, 143 (1920).

The FCA provides that the defendant shall be liable for three times the damages sustained by the government, plus a mandatory civil penalty of between \$5,500 and \$11,000 for each false claim. 31 U.S.C. § 3729(a); *see also* 28 C.F.R. § 85.3(a)(9) (adjusting penalties for inflation). In addition, the defendant is liable to the relator for his reasonable attorneys’ fees, costs, and expenses. 31 U.S.C. § 3730(d).

## **B. The Stark Statute.**

### **1. Basics.**

The Stark statute, codified at 42 U.S.C. § 1395nn, prohibits a hospital from submitting claims to Medicare based on referrals from physicians who have a “financial relationship” with the hospital, unless a specific statutory or regulatory exception applies. The Third Circuit has succinctly stated the basics of the Stark statute:

The Stark Act prohibits the presentation of a claim to Medicare for a designated health service by an entity where the service was furnished pursuant to a prohibited referral by a physician that has a financial relationship with the entity. *See* 42 U.S.C. § 1395nn(a). Under §1395nn(a)(1)(A), a physician may not refer Medicare patients to an entity for “designated health services,” including inpatient and outpatient hospital services, if the referring physician has a nonexempt “financial relationship” with such entity. Under § 1395nn(a)(1)(B), the entity is prohibited from presenting or causing to be presented a Medicare claim for services furnished pursuant to a prohibited referral. With certain exceptions, “financial relationship” is defined as (1) an ownership or investment interest

in the entity, or (2) a compensation arrangement with the entity. 42 U.S.C. § 1395nn(a)(2). *See generally United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 901-02 (5th Cir. 1997) (describing the operation of the Stark Act).

*United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 239 n.6 (3d Cir. 2004); *see also* 64 Fed. Reg. 63518, 63539 (“The Stark Law prohibits Medicare payment where physicians make referrals for designated health services to entities in which they have an ownership interest or with which they have a compensation arrangement, unless that interest or arrangement meets the strict terms of a statutory exception.”); 66 Fed. Reg. 856, 863 (“A physician cannot (1) refer patients to an entity (2) for the furnishing of DHS (3) if there is a financial relationship between the referring physician (or an immediate family member of the referring physician) and the entity, (4) unless the financial relationship fits within one of the specific exceptions in the statute or regulations issued by the Secretary.”).

Once the existence of a financial relationship has been established, “the burden shifts to the defendant to establish that his conduct was protected by a safe harbor or exception; the United States need not prove, as an element of its case, that defendant’s conduct does not fit within a safe harbor or exception.” *United States v. Rogan*, 459 F. Supp. 2d 692, 716 (D. Ill. 2006), *affirmed*, 517 F.3d 449 (7<sup>th</sup> Cir. 2008); *United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 2007 U.S. Dist. LEXIS 84294, \*26 (M.D. Pa. Nov. 14, 2007) (“When a financial relationship exists, the defendant incurs the burden of demonstrating the applicability of an exception.”); *see also United States v. Shaw*, 106 F. Supp. 2d 103, 122 (D. Mass. 2000). The statute and regulations contain several such exceptions, including exceptions for equipment rentals, 42 U.S.C. § 1395nn(e)(1)(B) and 42 C.F.R. § 411.357(b); space rentals, 42 U.S.C. § 1395nn(e)(1)(A) and 42 C.F.R. § 411.357(a); and indirect compensation arrangements, 42 C.F.R. § 411.357(p).

Because a hospital is expressly precluded from submitting claims to Medicare based on prohibited referrals, the knowing submission of such claims constitutes a violation of the False Claims Act. *See Rogan, supra*, 459 F. Supp. 2d at 717-718 (D. Ill. 2006) (“The submission of UB-92s in violation of the Stark Statute constitutes a violation of the FCA”); *see also Zimmer, supra*; *United States ex rel. Pogue v. Diabetes Treatment Centers of America*, 238 F. Supp.2d 258, 266 (D.D.C. 2002) (“The Stark laws . . . specifically state that compliance is required in order to receive Medicare reimbursement.”); *see also* 66 Fed. Reg. 856, 859-60 (“knowingly submitting a claim in violation of the prohibition, can be punished through . . . the False Claims Act”).

## **2. “Direct” vs. “indirect” compensation arrangements.**

The Stark statute itself does not distinguish between “direct” and “indirect” compensation arrangements, but simply defines “compensation arrangement” as “any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity other than an arrangement involving only remuneration described in subparagraph (C).” 42 U.S.C. § 1395nn(h)(1)(A). “Remuneration,” in turn, is defined to “include[] any remuneration, directly or indirectly, overtly or covertly, in cash or in kind.” 42 U.S.C. § 1395nn(h)(1)(B). Thus, the statute does not set forth different requirements for “direct” and “indirect” compensation agreements, but rather recognizes that even “indirect” remuneration is sufficient to create a compensation arrangement, and hence a financial relationship.

The Stark regulations, by contrast, distinguish between “direct” and “indirect” compensation arrangements. The term “compensation arrangement” is defined as “any arrangement involving remuneration, direct or indirect, between a physician (or a member of a physician’s immediate family) and an entity.” 42 C.F.R. § 411.354(c). Prior to December 5, 2007, the effective date of the Stark Phase III regulations, the regulations did not contain a separate definition of “direct

compensation arrangement,” but did contain the following definition of “indirect compensation arrangement”:

(2) Indirect compensation arrangement. An indirect compensation arrangement exists if

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(i) Between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships (as defined in paragraph (a) of this section) between them (that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link);

(ii) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS, regardless of whether the individual unit of compensation satisfies the special rules on unit-based compensation under § 411.354(d)(2) or (d)(3). If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the nonownership or noninvestment interest closest to the referring physician (or immediate family member). (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii)); and

(iii) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.

42 C.F.R. § 411.354(c)(2) (emphasis added). Thus, in order to constitute an “indirect compensation arrangement,” the compensation must “var[y] with, or otherwise reflect[], the volume or value of



referrals or other business generated by the referring physician for the entity furnishing the DHS.”<sup>4</sup>

This requirement does not exist if the remuneration flows directly to the physicians, and therefore constitutes a direct compensation arrangement. Thus, the definition of “indirect compensation arrangement” in the regulations created a “loophole” that physicians could seek to exploit by simply routing any remuneration through their professional practice rather than to them individually.

In September 2007, CMS issued its Phase III regulations under the Stark statute, which sought to close this loophole. The new regulations, as recently modified, provide a definition of “direct compensation arrangement,” and also provide that a physician “stands in the shoes” of his physician practice:

(1)(i) A direct compensation arrangement exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities.

(ii) Except as provided in paragraph (c)(3)(ii)(C) of this section, a physician is deemed to stand in the shoes of his or her physician organization and have a direct compensation arrangement with an entity furnishing DHS if--

(A) The only intervening entity between the physician and the entity furnishing DHS is his or her physician organization; and

(B) The physician has an ownership or investment interest in the physician organization.

42 C.F.R. § 411.354(c)(1). Thus, many arrangements which previously might not have met the definition of “indirect compensation arrangement” are now considered “direct compensation

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<sup>4</sup> The language of 42 C.F.R. § 411.354(c)(2)(ii) was modified effective December 2007 to change the term “otherwise reflects” to “takes into account.” CMS made clear that this change was non-substantive, and that the terms had the same meaning. 72 Fed. Reg. 51012, 51027 (“In addition, we are making non-substantive changes to clarify that we do not interpret ‘otherwise reflects’ and ‘takes into account’ (with respect to referrals and as these terms are used in certain exceptions) as having separate and different meanings. That is, the terms were used interchangeably in Phase II, and we have made conforming changes for consistency.”).

arrangements,” and there is no need to determine whether the remuneration varies with or otherwise reflects referrals. The effective date for the new regulations was December 4, 2007.<sup>5</sup>

**C. The Anti-Kickback Statute.**

The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), makes it illegal to knowingly offer, pay, solicit, or receive remuneration for referrals of services covered by a federal health care program. The statute states as follows:

(b) Illegal remunerations.

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$ 25,000 or imprisoned for not more than five years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person--

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$ 25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b).

As the Third Circuit and other courts have recognized, the statute is violated if one purpose of the remuneration is to induce such referrals. *See United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985) (“If the payments were intended to induce the physician to use Cardio-Med’s services,

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<sup>5</sup> CMS delayed the applicability of the new regulations until December 4, 2008 for certain academic medical centers and integrated Section 501(c)(3) health care systems. 72 Fed. Reg. 64161. This

the statute was violated, even if the payments were also intended to compensate for professional services.”); *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); 66 Fed. Reg. 856, 918 (“If any one purpose of remuneration is to induce or reward referrals of Federal health care program business, the statute is violated.”).

Similar to the exceptions under the Stark statute, the regulations implementing the Anti-Kickback Statute contain a number of “safe harbors,” which serve to insulate conduct that might otherwise be found to violate the statute. These include safe harbors for equipment rentals, 42 C.F.R. § 1001.952(c); and space rentals, 42 C.F.R. § 1001.952(b).

As has repeatedly been recognized,

[c]laims submitted in violation of the [Anti-Kickback] Act qualify as ‘false claims’ under the FCA, even if no criminal prosecution follows the alleged violation. See *United States ex rel. Showell v. Philadelphia AFL, CIO Hosp. Ass’n*, No. CIV.A. 98-1916, 2000 U.S. Dist. LEXIS 4960, 2000 WL 424274, at \*7 (E.D. Pa. Apr. 18, 2000); see also *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 238 F. Supp. 2d 258, 263 (D.D.C. 2002); cf. *McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1260 (11th Cir. 2005) (upholding denial of motion to dismiss under the FCA because government alleged violation of Anti-Kickback Act, which was sufficient to state a claim under the FCA); *Schmidt*, 386 F.3d at 239- 40, 244 (reversing district court’s dismissal of an FCA suit based on violations of Stark and Anti-Kickback Acts).

*United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 2007 U.S. Dist. LEXIS 84294, \*43 (M.D. Pa. Nov. 14, 2007).

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delay has no effect on this case.

**III. RELATORS ARE ENTITLED TO SUMMARY JUDGMENT ON THEIR CLAIMS THAT DEFENDANTS VIOLATED THE STARK STATUTE.**

As discussed above, if a “financial relationship” exists between a physician and a hospital, the physician may not make referrals to the hospital for designated health services, and the hospital may not submit claims to Medicare based on such referrals, unless the arrangement falls within an exception set forth in the Stark statute and accompanying regulations. The undisputed evidence in this case clearly establishes that there is a financial relationship between BRMC, on the one hand, and Drs. Vaccaro and Saleh, on the other. The evidence also demonstrates that no statutory exception applies. Accordingly, Relators are entitled to summary judgment that all claims based on a referral from Drs. Vaccaro and Saleh violate the Stark statute, and thus constitute false claims.

**A. There is a “direct financial relationship” between BRMC and Drs. Vaccaro and Saleh.**

Defendants have asserted that the only “direct” financial relationship in this case is between BRMC and V&S, and that any relationship between BRMC and the individual physicians can only be “indirect.” As discussed below, this assertion is simply false. The record clearly demonstrates that Drs. Vaccaro and Saleh have direct financial relationships with the hospital, both as a result of the sublease arrangement and through separate personal service contracts. Accordingly, it is not necessary to consider whether the sublease arrangement meets the definition of an “indirect compensation arrangement” (although, as discussed below, the arrangement does in fact meet such definition). Because Drs. Vaccaro and Saleh have direct compensation arrangements with the hospital, they are precluded from making referrals to the hospital for designated health services, and the hospital is precluded from submitting claims to Medicare based on such referrals, unless they satisfy the conditions of a Stark exception.

**1. Drs. Vaccaro and Saleh individually are parties to the sublease arrangement.**

As an initial matter, contrary to Defendants' suggestions, the sublease arrangement is not simply an arrangement between the hospital and V&S – rather, it is an arrangement between the hospital, V&S, and Drs. Vaccaro and Saleh individually. Indeed, the sublease arrangement was initially embodied in an Agreement dated April 16, 2003. Drs. Vaccaro and Saleh individually signed this Agreement, agreeing to be bound by its terms. Saleh Dep., p. 160 and Exhibit 31; Vaccaro Dep., p. 49 (Apx., Docs.3, 37, 4). When the final Equipment Sublease was executed on October 1, 2003, it stated that “Kamran Saleh, M.D. and Peter Vaccaro, M.D., as individuals residing in the Commonwealth of Pennsylvania, also agree to be bound by the terms and conditions of Section 14 of this Sublease.” This provision is signed by Drs. Saleh and Vaccaro individually. Saleh Dep., p. 163 and Exhibit 32; Vaccaro Dep., p. 49 (Apx., Docs.3, 12, 4). As Dr. Saleh testified, this provision prevented him individually, and not simply V&S, from opening a competing business. Saleh Dep., p. 163-64 (Apx., Doc. 3). Thus, the sublease arrangement is not simply between the hospital and V&S, but the doctors themselves are also parties to the arrangement. And as discussed in the next section, Drs. Vaccaro and Saleh received substantial benefits individually from the arrangement.

**2. The sublease arrangement relieved Drs. Vaccaro and Saleh of personal liability under their guaranties to GE, and thus constituted substantial remuneration to them individually.**

When V&S leased its nuclear camera from GE, Drs. Vaccaro and Saleh each executed a guaranty of V&S's obligations to GE, and thus were personally responsible for all payments under the lease. (Apx., Doc. 50, at V&S00375-00378, V&S00383, V&S02267-02270, V&S00681-00684). When BRMC entered into the Equipment Sublease, therefore, and agreed to make “pass-through” payments of all amounts due to GE, it conferred a substantial economic benefit upon Drs. Vaccaro and Saleh individually, as well as upon V&S as a company. Similarly, when BRMC

agreed to fund the early termination of the GE lease, it relieved Drs. Vaccaro and Saleh of hundreds of thousands of dollars of personal liability under the GE lease.

As discussed above, “[a] compensation arrangement is any arrangement involving remuneration, direct or indirect, between a physician ... and an entity.” 42 C.F.R. § 411.354(c). “Remuneration” includes “any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind.” 42 C.F.R. § 411.351 (emphasis added). Clearly, relieving an individual of personal liability on a debt constitutes a substantial economic benefit, and thus constitutes remuneration directly to the individual. Accordingly, because the sublease arrangement provided remuneration to Drs. Vaccaro and Saleh individually, as well as to V&S, it constitutes a direct compensation arrangement between BRMC and Drs. Vaccaro and Saleh.

**3. Since December 4, 2007, all arrangements between the hospital and V&S constitute “direct compensation arrangements” with Drs. Vaccaro and Saleh.**

As discussed above, the sublease arrangement created a direct financial relationship between BRMC, on one hand, and Drs. Vaccaro and Saleh, on the other, since BRMC provided substantial remuneration to the doctors individually. Even apart from this fact, however, a direct financial relationship has existed since at least December 4, 2007, when the Stark regulations were changed to provide that a physician “stands in the shoes” of his professional organization.

42 C.F.R. § 411.354(c)(1)(ii).

The undisputed evidence establishes that the sublease arrangement between the hospital and V&S continues to the present. Pursuant to that arrangement, the hospital continues to reimburse V&S for its lease payments on the Philips camera, and continues to pay V&S the “noncompete” payments set forth in the Equipment Sublease. Moreover, the hospital continues to reimburse V&S for its payments to Philips for the buyout of the GE lease. Leonhardt Dep., p. 81-82, 89 (Apx., Doc. 1). Because Drs. Vaccaro and Saleh “stand in the shoes” of V&S, it is undisputed that, since

December 4, 2007, a direct compensation arrangement has existed between them and the hospital as a result of the sublease arrangement.

**4. Drs. Vaccaro and Saleh each have personal service contracts with the hospital, apart from the sublease arrangement.**

It must also be noted that the sublease arrangement is not the only arrangement between the hospital and Drs. Vaccaro and Saleh. In addition, the doctors have each had personal service contracts with BRMC, under which they are paid thousands of dollars monthly.

Since at least January 1, 2006, Dr. Saleh has had a contract with BRMC to serve as a Case Management Medical Director. Under these agreements, Dr. Saleh is paid \$2,000 per month by BRMC. Saleh Dep., p. 172-175 (Apx., Doc. 3). Dr. Saleh testified that he had a similar contract for a period of time before January 1, 2006, although he could not remember how long before. *Id.*, p. 175. In addition, since at least March 1, 2006, Dr. Saleh has had a separate contract with BRMC to provide certain internal medicine services for Bradford Recovery Systems, for which he is paid a specified amount. *Id.*, p. 170-176. Dr. Saleh testified that he might have had a similar agreement prior to March 1, 2006. *Id.*, p. 172-173.

Since at least March 1, 2006, Dr. Vaccaro has had a contract with BRMC to provide certain internal medicine services for Bradford Recovery Systems, for which he is paid \$2,000 per month. Vaccaro Dep., p. 50-52 (Apx., Doc. 4). Dr. Vaccaro testified that he might have had a similar contract for a prior year. *Id.*, p. 52.

Separate and apart from the sublease arrangement, these personal service contracts clearly constitute direct financial relationships between the hospital and the doctors. Accordingly, the hospital is prohibited from submitting Medicare claims based on referrals from these physicians unless they can demonstrate the applicability of a Stark exception.

**B. An “indirect financial relationship” existed between BRMC and Drs. Vaccaro and Saleh.**

The above discussion demonstrates that a direct compensation arrangement has existed, and continues to exist, between Drs. Vaccaro and Saleh and BRMC. Accordingly, it is not necessary to determine whether the arrangement also constitutes an “indirect compensation arrangement.” However, the undisputed evidence demonstrates that an indirect compensation arrangement has in fact existed since the execution of the Equipment Sublease.<sup>6</sup>

As discussed above, unlike a direct compensation arrangement, an indirect compensation arrangement requires that the aggregate compensation received by the physician “varies with, or otherwise reflects,<sup>7</sup> the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.” 42 C.F.R. § 411.354(c)(2)(ii). In the present case, this determination is measured by the aggregate compensation from BRMC to V&S.<sup>8</sup>

In order to constitute an “indirect compensation arrangement,” therefore, it is not necessary that the payments vary with the volume or value of referrals or other business – it is sufficient if the payments “otherwise reflect” or “take into account” such volume or value. Otherwise, the parties

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<sup>6</sup> Of course, as discussed above, any indirect compensation arrangement would have been transformed into a direct compensation arrangement on December 4, 2007, the effective date of the Phase III regulations.

<sup>7</sup> As discussed above, the term “otherwise reflects” was changed to “takes into account” in December 2007, although CMS made it clear that the terms have the same meaning. 72 Fed. Reg. 51012, 51027.

<sup>8</sup> See 42 C.F.R. § 411.354(c)(2)(ii) (“If the financial relationship between the physician ... and the person or entity in the chain with which the referring physician ... has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the nonownership or noninvestment interest closest to the referring physician.”) (emphasis added). Because Drs. Vaccaro and Saleh have a direct ownership interest in V&S, we must look at the compensation paid from BRMC to V&S.



could circumvent the prohibition simply by fixing a payment based on the expected volume of referrals, rather than having the payments vary directly with such referrals.<sup>9</sup>

The regulations and accompanying guidance leave no doubt that a payment reflects the volume or value of referrals if it takes into account anticipated referrals from the physician. For example, the definition of “fair market value” expressly requires that “the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.” 42 C.F.R. § 411.351 (emphasis added). CMS has expressly stated that “the ‘volume and value’ condition prohibits the amount of assistance payable to the physician or the group practice from taking into account, in any manner, the volume or value of past or anticipated referrals to the hospital.” 72 Fed. Reg. 51012, 51048 (emphasis added). CMS has also stated that it “will not consider the volume or value standard implicated” in certain circumstances, but only if various conditions are met, including that “the payment does not take into account the volume or value of the anticipated or required referrals.” 66 Fed. Reg. 856, 877 (emphasis added).<sup>10</sup> It is abundantly clear, therefore, that the “volume or value” standard is implicated if a payment takes into account anticipated referrals.<sup>11</sup> And as discussed below, there is simply no doubt that the payments to V&S under the sublease arrangement took into account the anticipated referrals from

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<sup>9</sup> Indeed, this was one of the grounds for Defendants’ previous motion to dismiss, which was denied by the Court. *See* Defendants’ Memorandum in Support of Joint Motion to Dismiss, Docket No. 14, p. 14-17; Response to Defendants’ Joint Motion to Dismiss, Docket No. 24, p. 13-15; Opinion, Docket No. 31, p. 11-12.

<sup>10</sup> CMS has noted that the “volume or value” standard appears in a number of different places in the statute and regulations, and that its interpretation of that standard uniformly applies to all such situations, including indirect compensation arrangements. 66 Fed. Reg. 856, 877.

<sup>11</sup> CMS’s comments regarding the Anti-Kickback Statute also reflect concerns about “anticipated” referrals. For example, in its supplemental compliance program guidance for hospitals, CMS notes that, in assessing compensation agreements between hospitals and physicians, one question suggesting possible fraud is “Were the physicians selected to participate in the arrangement in whole or in part because of their past or anticipated referrals?” 69 Fed. Reg. 32012, 32021.

Drs. Vaccaro and Saleh.<sup>12</sup>

1. **BRMC acknowledges that the compensation provided under the Equipment Sublease took into account referrals from Drs. Vaccaro and Saleh.**
  - a. **BRMC's own fair market value assessment explicitly took into account anticipated referrals from Drs. Vaccaro and Saleh.**

Before entering into the Equipment Sublease, BRMC had a “fair market value” assessment prepared by an accountant, Charles Day. The purported purpose of this report was to determine whether BRMC was paying fair market value under the proposed sublease arrangement, and George Leonhardt testified that he considered and relied on this report before executing the Equipment Sublease. BRMC 30(b)(6) Dep., p. 147-48; Leonhardt Dep., p. 55-56 (Apx., Docs. 2, 1).

In the report, Mr. Day noted that the purpose of the noncompete payments was to “protect” certain “revenue streams” flowing from V&S:

There are three revenue streams that the Board felt would be severely impacted if physicians had financial interests that would induce them to direct business away from the hospital and that needed to be protected by associating a covenant not to compete with the sublease. These are CT and MRI net revenues, inpatient net revenues and outpatient net revenues (excluding the aforementioned CT and MRI net revenues).

Leonhardt Dep., p. 57 and Exhibit 4, p.14 (Apx., Docs. 1, 7). In other words, the purpose of the noncompete payments was to “protect” referrals from V&S – i.e., to ensure that V&S would refer such business to the hospital, rather than performing tests itself or referring patients elsewhere.

In performing his fair market value analysis, Mr. Day compared the revenues BRMC expected to generate with the sublease in place to the revenues it expected to receive without the

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<sup>12</sup> There is another element in the “indirect compensation arrangement” definition, namely that BRMC “has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician ... receives aggregate compensation that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.” 42 C.F.R. § 411.354(c)(2). In the present case, this element is easily satisfied, since BRMC is the entity providing the compensation to V&S.

sublease in place. The revenues in question consisted of referrals from V&S, and the projections were based on the expectation that V&S would refer such business to the hospital if the sublease arrangement were approved. Indeed, the report expressly admitted that:

the table shows the expected quantitative revenues that would accrue to the hospital with a noncompetition agreement in place and a comparison of those benefits to the amounts payable under the noncompetition agreement. This is based on the assumption that the physicians would likely refer this business to the hospital in the absence of a financial interest in their own facilities or services, although they are not required to do so by virtue of any of the covenants contained in the Agreements or otherwise.

Leonhardt Dep., p. 55 and Exhibit 4, p. 17 (Apx., Doc. 1, 7) (emphasis added). Thus, BRMC's own fair market value analysis was expressly based on the projection of anticipated referrals from V&S.

In his deposition, George Leonhardt confirmed that the report was based on the projection that V&S would refer business to the hospital following execution of the sublease:

Q. So this agreement is evaluating the expected revenues from entering into the lease agreement and it's based on the assumption that V&S is likely going to refer that business to the hospital; is that correct?

A. That's how I read it, yes.

Q. And you relied upon that in evaluating fair market value -- in evaluating whether the price you were paying to V&S was a fair market value?

A. Yes.

Leonhardt Dep., p. 56 (Apx., Doc. 1). In BRMC's 30(b)(6) deposition, Mr. Leonhardt similarly confirmed that the fair market value analysis was based on the projection of referrals from V&S:

Q. ... In other words, Mr. Day is relating the value that you are paying here to the benefit that the hospital is receiving from having the covenant not to compete; isn't that right?

A. Yes.

Q. And that is based on the additional business that the hospital has; isn't that right?

MR. MULHOLLAND: Objection. Assumes facts not in the record. You can answer.

A. It is based on the opportunity for that additional business, yes.

Q. The expectation?

A. The hope.

Q. Well --

A. The hope.

Q. Well, according to this, the projection of the prospective cash flow?

A. Yes.

BRMC 30(b)(6) Dep., p. 156 (Apx., Doc. 2); *see also* Leonhardt Dep., p. 57 (“Q. You did more than hope. You expected they would refer to you? A. Expected they would refer a good bit of it to us, yeah.”) (Apx., Doc. 1). BRMC had substantial justification for its expectation that V&S would refer their nuclear imaging patients to the hospital. During negotiations over the lease arrangement, V&S’s attorney assured BRMC that “[m]y clients have indicated that all of their Nuclear Medicine Studies can be accommodated by a combination of their current camera and those at BRMC.” Leonhardt Dep., p. 37 and Exhibit 2 (at V&S 01629) (Apx., Docs. 1, 40).

By its own admission, therefore, BRMC manifestly took the anticipated referrals from V&S into account in analyzing the payments under the sublease arrangement. Indeed, BRMC’s own fair market value analysis is, in effect, nothing more than a straightforward comparison of the anticipated referrals from V&S with and without the sublease in place. It is difficult to imagine a scenario that could more straightforwardly reflect anticipated referrals. In fact, the anticipated referrals were the only thing that made the arrangement attractive, and George Leonhardt admitted that he would not have done the deal except for the expectation of referrals. Leonhardt Dep., p. 53 (Apx., Doc. 1).

**b. Mr. Leonhart relied on projections of V&S’s nuclear cardiology referrals in presenting the sublease to the board.**

George Leonhardt testified that he had to obtain board approval to enter into the sublease arrangement. Leonhardt Dep., p. 65-66 (Apx., Doc. 1). He prepared a summary of the sublease arrangement to present to the board. *Id.*, p. 66-68 and Exhibit 5 (Apx., Docs. 1, 8). The financial part of this summary stated as follows:

**Financial Background:**

- BRMC's current margin on Nuclear Medicine is \$132,000
- *Adding a portion of V&S volume to BRMC's current volumes:*

*Lease of V&S Equipment:*

BRMC Profit:	\$402,000
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V&S Profit:	\$268,000
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*When finalized, the Under Arrangements Model:*

BRMC Profit:	\$372,000
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Physician Newco Profit:	\$282,000
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Leonhardt Dep., p. 71 and Exhibit 5 (Apx., Docs. 1, 8) (italics added). In his deposition, Mr.

Leonhardt testified that these figures referred to the expected profit from adding V&S's anticipated nuclear medicine referrals to the hospital's current nuclear medicine volumes:

Q. Do you see where it says "Adding a portion of V&S volume to BRMC's current volumes"? That's talking about the expectation that at least a portion of V&S's business is going to be coming to the hospital; correct?

A. That's correct.

Q. And then it says, "Lease of V&S equipment, BRMC Profit, 402,000, V&S Profit 268,000." Is that the expected profit to Bradford from entering into this lease agreement?

A. I would expect that's the profit that we assumed from that volume of services, yes.

Q. From adding a portion of V&S's volume?

A. Yeah.

...

Q. So from these numbers it looks like the lease is more profitable to Bradford [than an Under Arrangements Model]; correct?

A. Yes; but the Under Arrangements Model had many more components than just nuclear cardiology.

Q. Correct. But here you're just comparing that component?

A. Here we're only comparing that component.

Leonhardt Dep., p. 71-72 (Apx., Doc. 1). Leonhardt testified that he made a presentation to the board based on this summary and obtained formal approval for the sublease arrangement. *Id.*, p. 72.

Leonhardt thus acknowledged that, in selling the lease proposal to the board, he focused on the additional profit that the hospital would earn from V&S making anticipated nuclear cardiology referrals to the hospital. Not coincidentally, the anticipated annual profit from such V&S referrals – \$402,000 – is slightly higher than the \$362,400 annual amount BRMC would have to pay under the Equipment Sublease. In short, BRMC estimated that it would pay \$362,400 in sublease payments, and in return would get \$402,000 profit from the additional nuclear cardiology referrals anticipated from V&S.

Clearly, therefore, BRMC took into account the anticipated referrals from V&S in evaluating the payments under the sublease arrangement. Indeed, the anticipated referrals were the whole point of the arrangement, and Leonhardt admitted that he would not have done the deal except for the expectation of referrals. Leonhardt Dep., p. 53 (Apx., Doc. 1).

**2. The “10% billing fee” arrangement, in effect from October 2003 through June 2004, directly varied with the volume and value of referrals.**

The above discussion demonstrates that the payments under the sublease arrangement manifestly reflected the anticipated referrals from Drs. Vaccaro and Saleh. Accordingly, the arrangement satisfies the definition of an “indirect compensation arrangement.” Separate and apart from this fact, however, the undisputed evidence establishes that, for a substantial period of time, the payments from BRMC to V&S directly varied with the referrals or other business generated by V&S, thus providing an additional basis for finding an indirect compensation arrangement.

As discussed above, for several months after the execution of the October 1, 2003 Equipment Sublease, the GE camera remained at V&S’s facility, even though it had been subleased by BRMC. BRMC paid V&S \$2,500 per month rent to keep the camera in its office, as well as paying certain amounts for secretarial support, utilities, and other items. During that period, V&S used the machine almost exclusively to perform tests on their own patients, as they had done

previously. Leonhardt Dep., p. 86; Vaccaro Dep., p. 26; Saleh Dep., p. 54-55 (Apx., Docs. 1, 4, 3).

V&S handled the billing and collections for those tests, and charged BRMC a “billing fee” equal to 10% of all amounts collected on such claims. V&S would collect all the billings, subtract out the 10% billing fee and the various rental and associated charges, and remit the balance to BRMC (or BRMC would write a check to V&S if the billing fee and rental charges exceeded the collections). Saleh Dep., p. 151-160 and Exhibit 30; *see also* Leonhardt Dep., p. 79-80 (Apx., Docs. 3, 1).

V&S began performing such tests upon the execution of the Equipment Sublease on October 1, 2003, and continued billing BRMC for the 10% billing fee through at least June 2004. V&S billed BRMC the following amounts for billing services, based upon its collections:

<u>Statement Date</u>	<u>Amount</u>
November 2003	\$2,492.23
December 2003	\$2,764.27
January 2004	\$4,243.84
March 2004	\$2,926.83
April 2004	\$817.33
June 2004	\$3,075.57

Saleh Dep., p. 151-160 and Exhibit 30 (Apx., Docs. 3, 41).

Quite clearly, the amounts paid by BRMC to V&S for the 10% billing fee directly varied with the volume or value of referrals or other business generated by V&S – i.e., the more tests that were ordered and performed by V&S, the more money was collected, and the greater the billing fee received by V&S. Or to put it more simply, the more business V&S generated for BRMC, the more money V&S earned on the billing fees. Indeed, it is difficult to conceive of a payment that varies more directly with referrals or other business than one in which the referring physicians are paid a percentage of collections. Thus, during the period when this “10% billing fee” was in effect, there is simply no dispute that an indirect compensation arrangement existed between BRMC and Drs. Vaccaro and Saleh.

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As discussed above, the undisputed evidence clearly establishes that a direct and/or indirect financial relationship has existed between BRMC, on the one hand, and Drs. Vaccaro and Saleh, on the other. Such financial relationship continues to the present day. Accordingly, Drs. Vaccaro and Saleh are prohibited from making referrals to BRMC for designated health services, and BRMC is prohibited from submitting claims to Medicare based on such referrals, unless the Defendants can establish the applicability of a Stark exception. And as discussed in detail below, no such exception applies.

**C. Defendants cannot satisfy any exception.**

Once a financial relationship has been established, “the burden shifts to the defendant to establish that his conduct was protected by a safe harbor or exception; the United States need not prove, as an element of its case, that defendant’s conduct does not fit within a safe harbor or exception.” *United States v. Rogan*, 459 F. Supp. 2d 692, 716 (D. Ill. 2006), *affirmed*, 517 F.3d 449 (7<sup>th</sup> Cir. 2008); *United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 2007 U.S. Dist. LEXIS 84294 (M.D. Pa. Nov. 14, 2007) (“When a financial relationship exists, the defendant incurs the burden of demonstrating the applicability of an exception.”); *see also United States v. Shaw*, 106 F. Supp. 2d 103, 122 (D. Mass. 2000).

In discovery, Relators asked Defendants to identify any Stark exceptions they contended might apply in this case. The only exception identified by BRMC was the exception for equipment rentals set forth in 42 U.S.C. § 1395nn(e)(1)(B) and 42 C.F.R. § 411.357(b). BRMC’s Response to Plaintiffs’ First Interrogatories, No. 2 (Apx., Doc. 43). The only exceptions identified by V&S were the equipment rental exception and the exception for indirect compensation arrangements, 42 C.F.R. § 411.357(p). V&S Defendants’ Objections and Responses to Plaintiffs’ First Interrogatories, p. 6 (Apx., Doc. 42). As discussed below, Defendants cannot meet the requirements of either of these



exceptions. Although not identified by Defendants, Relators show that they also cannot satisfy the exception for space rentals set forth in 42 U.S.C. § 1395nn(e)(1)(A) and 42 C.F.R. § 411.357(a).

**1. The equipment rental exception does not apply.**

The Stark statute contains an exception for payments made for equipment rental, provided that numerous conditions are met:

(B) Equipment. Payments made by a lessee of equipment to the lessor of the equipment for the use of the equipment if--

- (i) the lease is set out in writing, signed by the parties, and specifies the equipment covered by the lease,
- (ii) the equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee,
- (iii) the lease provides for a term of rental or lease of at least 1 year,
- (iv) the rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,
- (v) the lease would be commercially reasonable even if no referrals were made between the parties, and
- (vi) the lease meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

42 U.S.C. § 1395nn(e)(1)(B). The regulations issued under the Stark statute contain a substantially identical exception, stating as follows:

(b) Rental of equipment. Payments made by a lessee to a lessor for the use of equipment under the following conditions:

- (1) A rental or lease agreement is set out in writing, is signed by the parties, and specifies the equipment it covers.
- (2) The equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee and is not shared with or used by the lessor or any person or entity related to the lessor.
- (3) The agreement provides for a term of rental or lease of at least 1 year. To meet this requirement, if the agreement is terminated during the term with or without cause, the parties may not enter into a new agreement during the first year of the original term of the agreement.
- (4) The rental charges over the term of the agreement are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.
- (5) The agreement would be commercially reasonable even if no referrals were made between the parties.

(6) A holdover month-to-month rental for up to 6 months immediately following an agreement of at least 1 year that met the conditions of this paragraph (b) will satisfy this paragraph (b), provided the holdover rental is on the same terms and conditions as the immediately preceding agreement.

42 C.F.R. § 411.357(b). As discussed below, the Defendants cannot satisfy many of the requirements of the exception.

**a. This exception only applies to payments for use of equipment.**

As an initial matter, this exception applies only to payments made by a lessee to a lessor for the use of equipment. In the present case, the only such payments consist of the “pass-through” payments made by BRMC to V&S for use of the GE and/or Philips nuclear cameras. The exception thus does not even arguably apply to the numerous additional payments made by BRMC to V&S for things other than the use of the nuclear cameras, including: (1) the \$23,655 per month “noncompete” payments; (2) the \$2,500 per month space rental paid by BRMC to keep the GE camera at V&S’s office; (3) the various other charges for secretarial support, etc. paid by BRMC in connection with such space rental; (4) the 10% billing fee paid by BRMC to V&S; and (5) the payments to Drs. Vaccaro and Saleh under their personal service contracts.

Similarly, this exception does not apply to the payments made by BRMC in connection with the early termination of the GE lease. As discussed above, Philips paid the \$200,000 early termination fee for the GE lease, and V&S agreed to repay Philips \$3,958.13 per month for 60 months (in addition to its payments for the lease of the Philips camera). BRMC guaranteed this obligation, and has reimbursed V&S every month for its payment to Philips. Although BRMC is the ultimate source for the buyout fee, it did not acquire ownership of the GE camera upon termination of the lease – rather, V&S acquired ownership of the camera. Nor did BRMC use the GE camera upon termination of the GE lease. Rather, the camera remained with V&S, which ultimately gave the camera away as a charitable donation to another hospital. In short, BRMC agreed to incur a

\$200,000 obligation in order to terminate the GE lease, so that V&S could obtain ownership of the camera to give it away to a competing hospital! Thus, BRMC's monthly payments to V&S in connection with the early termination of the GE lease – payments which continue to this day, years after BRMC stopped using the camera – can in no way be considered payments “for the use of the equipment.”

Because the equipment rental exception applies only to payments for the use of equipment, none of the above payments is even arguably covered by the exception. Accordingly, Defendants cannot rely on the equipment rental exception to negate the existence of a financial relationship.

**b. The GE equipment was not used exclusively by BRMC.**

In order to qualify for the exception, the equipment must be used exclusively by the lessee, and not shared with the lessor. That is emphatically not the case with respect to the GE camera. As discussed above, although the sublease expressly stated that “the Equipment will be moved to [BRMC],” the parties in fact left the camera in V&S's office. V&S continued to use the camera as it always had, performing tests for its own patients and retaining a 10% billing fee. In addition, V&S received additional payments in connection with its use of the camera, such as a \$2,500 space rental and associated charges. When BRMC agreed to pay for the early termination of the GE lease, it did not take possession of the camera, but left it with V&S, which ultimately made a charitable donation of the camera to another hospital. Thus, it is clear that the GE camera was not exclusively used by BRMC, but was either shared with V&S or used exclusively by V&S. Accordingly, Defendants cannot rely on the equipment rental exception.

c. **The agreement would not be commercially reasonable in the absence of referrals.**

In order to satisfy the equipment rental exception, Defendants must show that “[t]he agreement would be commercially reasonable even if no referrals were made between the parties.”

As CMS has stated:

An arrangement will be considered “commercially reasonable” in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were no potential DHS referrals.

69 Fed. Reg. 16054, 16093 (emphasis added). As discussed below, the only thing that makes the arrangement even arguably reasonable is the expectation of referrals from V&S; in the absence of such referrals, the arrangement is about as commercially unreasonable as could be imagined.

i. **BRMC incurred hundreds of thousands of dollars in rental charges and buyout fees to obtain the use of the GE camera for only four or five months, even though the camera only generated \$17,000 in income for BRMC during that period.**

At the time BRMC entered into the Equipment Sublease, it knew that the GE camera was not suited to its long-term needs. As BRMC’s 30(b)(6) designee testified, BRMC decided to leave the GE camera at V&S’s office because BRMC was aware it did not meet the hospital’s needs:

The GE camera was an older model with some limited technology, so we opted not to have that camera moved, because we did not feel that it would meet our future needs . . . . We informed [V&S] that that would not meet our future needs, because of the older technology and because of its nuclear cardiology limitations.

BRMC 30(b)(6) Dep., p. 74, 76 (Apx., Doc. 2). George Leonhardt testified that, at the time he entered into the sublease, “[w]e were aware that this was not going to be the camera we ultimately wanted.” Leonhardt Dep., p. 49 (Apx., Doc. 1).

Not only did BRMC know that the GE camera was unsuitable, but it also knew that it would shortly replace the GE camera with the Philips camera that it really wanted. Indeed, when asked

why BRMC decided to leave the GE camera at V&S's office upon the execution of the sublease, rather than moving it to the hospital, George Leonhardt responded, "Because we couldn't get the camera from Philips that we had wanted at the time that the lease was entered into. It took us longer to get that than we expected it to." Leonhardt Dep., p. 78; *see also id.*, p. 87 ("the reason that the camera continued to operate in Vaccaro and Saleh's office is that the Philips camera and the arrangement between Philips and GE took longer to accomplish than any of us anticipated.") (Apx., Doc. 1).

Nevertheless, even though (i) BRMC knew the GE camera was not suited to its long-term needs, and (ii) it knew that it would be replacing the GE camera almost immediately, BRMC agreed to sublease the GE camera from V&S for a five-year term, through September 30, 2008. Bizarrely, this term extended beyond the expiration of V&S's primary lease with GE, which only had three years remaining. In other words, BRMC agreed to sublease the GE camera for a term that extended two years longer than the primary lease between V&S and GE. In explaining what an attractive deal the lease was for V&S, BRMC's own attorney told V&S that "It is rare for hospitals in this date and fiscal climate to contract for even a three year period on any equipment, product or service." Steinberg Dep., p. 10-11 and Exhibit 1 (marked as Kabala Exhibit 1) (Apx., Docs. 6, 39). It is even rarer to sublease a piece of equipment for five years, particularly when (i) there are only three years remaining on the primary lease, and (ii) the hospital does not even want the equipment to begin with!

In an attempt to address the fact that it didn't want the GE camera, BRMC included an extremely vague and confusing provision in the sublease stating that BRMC could "change or upgrade the Equipment from GE or to change equipment vendor should either the need or the opportunity for such a change occur, at [BRMC's] discretion." Equipment Sublease, p. 4 (Apx., Doc. 12). The sublease did not spell out exactly how such a "change or upgrade" would work,

although it vaguely stated that:

such change will be done under two principles: (i) the change will not detrimentally affect the Sublessor [i.e., V&S] under this Sublease's terms (i.e., no higher rental costs or fees, etc.), and (ii) the Sublessor shall materially be in the same position as to the Equipment at the end of the Sublease as the Sublessor now stands to the GE equipment at the end of this Sublease.

*Id.* Notably, the agreement did not state what would happen to BRMC's obligations with respect to the GE camera if it elected to "upgrade" to a new camera. Would such obligations cease? Would they continue? Arguably, the agreement can be interpreted to mean that, "We can go out and get a new camera to replace the GE camera, but we will continue to pay you for the sublease of the GE camera – which means that we will be paying for two cameras instead of one." Indeed, that is exactly what happened.

Although the Equipment Sublease stated that the camera would be moved to the hospital, the parties in fact left the GE camera exactly where it had always been, in V&S's office. After several months, V&S leased the Philips camera, which was placed in the hospital, and BRMC has reimbursed V&S for its monthly rental payments to Philips. From April 2004 onward, the GE camera was not used for anything. Saleh Dep., p. 158 (Apx., Doc. 1). Nevertheless BRMC continued its payments under the sublease. Indeed, although the GE equipment was not being used, V&S continued to charge BRMC the \$2,500 monthly space rental fee through June 2004, as well as a \$1,000 secretarial fee in April and May. Saleh Dep., Exhibit 30 (at V&S 03165-03169) (Apx., Doc. 41). Ultimately, BRMC ended up funding a \$200,000 early termination of the GE lease.<sup>13</sup>

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<sup>13</sup> As discussed above, the early termination fee was actually paid by Philips, and V&S agreed to repay Philips in 60 monthly installments. BRMC guaranteed this obligation, and has reimbursed V&S each month for its payment to Philips. Thus, BRMC has effectively been paying the termination fee for the benefit of V&S, although V&S ended up with ownership of the camera.

Although BRMC paid the lease buyout fee, V&S retained ownership and possession of the camera – in essence, therefore, the payment of the buyout fee was a simple gift to Drs. Vaccaro and Saleh, and BRMC received nothing whatsoever in return.

To sum up, therefore, BRMC agreed to a five-year sublease of a camera that it knew would be replaced immediately, and which in fact was only used for four or five months. To obtain this short-term use of the GE camera, BRMC incurred (i) pass-through rental payments of \$6,545 per month, plus (ii) a \$200,000 early termination fee.<sup>14</sup> And how much income did the GE camera generate for BRMC during that period? Approximately \$17,000!<sup>15</sup> In other words, BRMC incurred hundreds of thousand of dollars in rental and early termination charges for the GE camera, in return for which it received about \$17,000 in revenues. Under no stretch of the imagination can this be considered a “commercially reasonable” transaction. Indeed, if you ignore the expectation of referrals from V&S, it is hard to imagine a more unreasonable transaction.

**ii. BRMC structured the transaction so that it ended up paying for two cameras, when it only needed one.**

At the time it entered into the sublease, BRMC had one nuclear camera of its own, and wanted to obtain a second camera. George Leonhardt acknowledged, however, that BRMC did not need three cameras. Leonhardt Dep., p. 49-50 (Apex, Doc. 1) (“Q. So you had one and you were looking at getting another one? A. Correct. Q. You didn’t want three? A. No.”). Thus, BRMC

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<sup>14</sup> This does not include the \$23,655 per month “noncompete payment” that BRMC also made to V&S.

<sup>15</sup> This amount may be determined from the invoices attached as Exhibit 30 to the Saleh Deposition. These invoices reflect that V&S made actual payments to BRMC (after deductions for space rental, 10% billing fee, and other charges) of the following amounts: \$4,593.94 (November 2003); \$4,317.68 (December 2003); \$7,652.33 (February 2004); \$6,715.37 (March 2004). For the October 2003 invoice, BRMC made a net payment to V&S of \$4,879.84. The final invoice in June 2004 showed an amount due from BRMC of \$1,090.29.

had a business need for, at most, one additional camera.<sup>16</sup> However, BRMC structured the sublease arrangement so that it ended up paying for two additional cameras, even though it admittedly only wanted one, and only ended up with one. It is difficult to imagine a more commercially unreasonable way of satisfying a purported need for one camera.

As discussed above, BRMC never intended to use the GE camera for long, and in fact only used it for a few months at V&S's office (and almost exclusively for V&S's patients). However, BRMC did not simply rent the GE camera for a few months – rather, it entered into a five-year sublease (even though V&S only had three years remaining on its primary lease). BRMC paid the pass-through rental amounts on the lease, and then agreed to reimburse V&S for the \$200,000 early termination fee to buy out the lease. Even then, BRMC did not take ownership or possession of the camera, but allowed V&S to keep the camera. V&S subsequently made a charitable donation of the camera to a competing hospital, at BRMC's expense. Thus, BRMC in effect purchased the GE camera, although it allowed V&S to maintain possession and ownership.

When BRMC “upgraded” to the Philips camera, it did not simply purchase the Philips camera itself, or enter into a direct lease with Philips. Rather, BRMC allowed V&S to lease the camera from Philips. BRMC guaranteed V&S's obligations under the lease, and continues to make monthly payments to V&S to reimburse it for its lease payments to Philips. In essence, therefore, BRMC is purchasing the Philips camera for V&S. Significantly, however, BRMC's payments for

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<sup>16</sup> Indeed, the only reason BRMC needed a second camera was to handle the extra referrals it would get from V&S if it entered into the sublease arrangement. Leonhardt Dep., p. 87 (“we didn’t have the capacity to accept and do the diagnostic work on Vaccaro and Saleh’s patients with only one camera”). This is further borne out by the fact that, after the execution of the sublease, BRMC left the GE camera in V&S's office, where it was used almost exclusively for V&S's patients. *Id.*, p. 78. Thus, the hospital did not need a second camera for its pre-existing business – it only needed a second camera to handle the extra business it would obtain from V&S as a result of entering into the sublease arrangement. This further demonstrates that the entire purpose of the arrangement was to obtain V&S's business.



the Philips camera are not in place of its payments for the GE camera – they are in addition to the GE payments. Indeed, to this very day, BRMC continues to make monthly payments to V&S for both the GE and the Philips cameras.

Thus, although BRMC acknowledges that it only wanted one additional camera, and although it has only had the use of one additional camera at a time (first the GE, then the Philips), it structured the arrangement with V&S in such a way that it incurred the obligation to pay for two additional cameras. There is simply no way that such an arrangement could be considered commercially reasonable on its own terms – indeed, it is difficult to imagine a more commercially unreasonable way of satisfying a need for one camera. George Leonhardt himself acknowledged that he was aware of no other situation where a hospital has structured a lease arrangement in this manner. Leonhardt Dep., p. 91 (Apx., Doc. 1).

**iii. Leonhardt acknowledged that he would not have done the deal without the expectation of referrals.**

Given the manifest commercial unreasonableness of the sublease arrangement, why would a hospital agree to lease a piece of equipment for five years, when it did not really want the equipment and knew that it would replace it in at most a few months? Why would a hospital structure the arrangement so that it would have to pay for two cameras, even though it only needed and obtained one? The answer, as George Leonhardt acknowledged, was that the hospital was not simply looking to acquire a piece of equipment, but had an expectation of substantial referrals from V&S:

Q. Well, Mr. Leonhardt, that is a fairly cumbersome way to go out and acquire a piece of equipment, wouldn't you agree?

A. Yes, if that was the only thing that we were trying to accomplish. Obviously, it wasn't the only thing that we were trying to accomplish.

BRMC 30(b)(6) Dep., p.140 (Apx., Doc. 2). Leonhardt acknowledged that he hoped and expected to receive substantial referrals from V&S as a result of the sublease arrangement. *Id.*, p. 146, 156; Leonhardt Dep., p. 57 (Apx., Doc. 1). Indeed, Leonhardt projected that BRMC would receive

\$402,000 in profit from the additional nuclear imaging referrals expected to be made by V&S – enough to make the arrangement profitable for BRMC. *Id.*, p. 71-72 and Exhibit 5 (Apx., Docs. 1, 8). And as discussed above, he had substantial basis for projecting such referrals, since V&S’s own attorney assured BRMC that “[m]y clients have indicated that all of their Nuclear Medicine Studies can be accommodated by a combination of their current camera and those at BRMC.” Leonhardt Dep., p. 37 and Exhibit 2 (at V&S 01629) (Apx., Docs. 1, 40).

Not only did Leonhardt project such substantial referrals, but he acknowledged that he would not have entered into the lease arrangement without such referrals. *Id.*, p. 53 (Apx., Docs. 2) (“if somehow we magically knew that no patients would be referred to us, no, I don’t suppose we would have done this”). As discussed above,

[a]n arrangement will be considered “commercially reasonable” in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were no potential DHS referrals.

69 Fed. Reg. 16054, 16093 (emphasis added). Even George Leonhardt, who made the decision to enter into the arrangement, acknowledges that the arrangement would not have made sense if there were no potential referrals. Clearly, therefore, Defendants cannot satisfy the “commercially reasonable” standard, and thus cannot rely on the exception.

**d. The equipment leased exceeds that which is reasonable and necessary for the legitimate business purposes of the lease or rental.**

In order to satisfy the exception, Defendants must show that “the equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental.” As discussed above, however, Defendants cannot possibly satisfy this exception. As Leonhardt acknowledges, the hospital was looking for one additional camera, but did not want two additional cameras. However, BRMC structured the sublease arrangement such that it incurred

the obligation to pay for two additional cameras. By definition, therefore, the equipment “exceed[ed] that which was reasonable and necessary for the legitimate business purposes of the lease or rental.”

e. **There is no written sublease agreement specifying the Philips camera, or setting the rental payments for such camera in advance.**

To qualify for the exception, there must be “[a] rental or lease agreement [that] is set out in writing, is signed by the parties, and specifies the equipment it covers.” Moreover, “the rental charges over the term of the lease [must be] set in advance.” The sublease arrangement manifestly does not satisfy these requirements.

The only sublease agreement between BRMC and V&S is the October 1, 2003 Equipment Sublease, which specifies the GE camera, but does not specify the Philips camera. Nor does the sublease “set in advance” the rental charges to be paid for the Philips camera. Indeed, the parties never executed a sublease for the Philips camera at all. Saleh Dep., p. 52-53, 164 (Apx., Doc. 3). The only document executed by BRMC in connection with the Philips camera was BRMC’s guaranty of V&S’s obligations under the Philips lease. However, a guaranty is not a sublease, since (i) it is not an agreement between BRMC and V&S, but an undertaking by BRMC in favor of Philips; (ii) it does not state that BRMC is subleasing the camera from V&S; (iii) it does not identify the term of any such sublease; and (iv) it does not identify the rental charges to be paid by BRMC to V&S. In fact, the guaranty does not impose an obligation on BRMC to pay anything at all to V&S – it simply provides that BRMC will stand as surety for V&S’s obligations to Philips. Indeed, guaranties are executed all the time without the guarantor making payments to the primary obligor. Thus, Defendants cannot satisfy the requirement of a written lease agreement with respect to the Philips camera.

For all of the above reasons, Defendants cannot rely on the equipment rental exception to negate the existence of a financial relationship.

**2. The space rental exception does not apply.**

Although Defendants have not identified it in their discovery responses, Relators anticipate that Defendants might attempt to rely in part on the “space rental” exception set forth in 42 U.S.C. § 1395nn(e)(1)(A) and 42 C.F.R. § 411.357(a). The statute sets forth the exception as follows:

- (A) Office space. Payments made by a lessee to a lessor for the use of premises if--
- (i) the lease is set out in writing, signed by the parties, and specifies the premises covered by the lease,
  - (ii) the space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee, except that the lessee may make payments for the use of space consisting of common areas if such payments do not exceed the lessee’s pro rata share of expenses for such space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using such common areas,
  - (iii) the lease provides for a term of rental or lease for at least 1 year,
  - (iv) the rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,
  - (v) the lease would be commercially reasonable even if no referrals were made between the parties, and
  - (vi) the lease meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

42 U.S.C. § 1395nn(e)(1)(A). The regulations set forth a substantially identical exception, as follows:

- a) Rental of office space. Payments for the use of office space made by a lessee to a lessor if there is a rental or lease agreement that meets the following requirements:
- (1) The agreement is set out in writing, is signed by the parties, and specifies the premises it covers.
  - (2) The term of the agreement is at least 1 year. To meet this requirement, if the agreement is terminated during the term with or without cause, the parties may not enter into a new agreement during the first year of the original term of the agreement.
  - (3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor), except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee’s pro

rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas.

(4) The rental charges over the term of the agreement are set in advance and are consistent with fair market value.

(5) The rental charges over the term of the agreement are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(6) The agreement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

(7) A holdover month-to-month rental for up to 6 months immediately following an agreement of at least 1 year that met the conditions of this paragraph (a) will satisfy this paragraph (a), provided the holdover rental is on the same terms and conditions as the immediately preceding agreement.

42 C.F.R. § 411.357(a).

**a. The exception applies only to payments for the use of office space.**

As an initial matter, this exception applies only to payments “for the use of premises” or “for the use of office space.” The only payments arguably covered by the exception are the \$2,500 space rental payments made by BRMC to V&S while the GE camera remained on V&S’s premises.

**b. There is no valid written agreement.**

In order to satisfy the exception, “the lease [must be] set out in writing, signed by the parties, and specif[y] the premises covered by the lease.” This requirement is emphatically not satisfied in this case, as there is no written lease agreement between the parties with respect to the V&S office space. On October 2, 2003, V&S sent BRMC a one-page letter purporting to summarize “the monthly charges for the nuclear facility while located at V&S Medical Associates.” Leonhardt Dep., Exhibit 8 (Apx., Doc. 11). However, this letter does not purport to be a lease agreement, but is simply a unilateral statement from V&S. Moreover, this letter is not “signed by the parties,” since it is not signed by BRMC. Nor does the letter “specif[y] the premises covered by the lease,” as required by the exception – indeed, there is no indication whatsoever of what premises are supposedly being rented.

**c. The lease term is not for more than one year.**

In order to satisfy the exception, “the lease [must] provide[] for a term of rental or lease for at least 1 year.” Even if the October 2, 2003 letter could somehow be characterized as a lease, it most emphatically does not provide for a lease term of at least one year. Indeed, it does not provide for any term, and BRMC ended up leasing V&S’s office space for less than a year. Accordingly, the parties cannot satisfy the space rental exception.

**3. The “indirect compensation arrangement” exception does not apply.**

The “indirect compensation arrangement” exception is set forth in 42 C.F.R. § 411.357(p), and provides as follows:

(p) Indirect compensation arrangements. Indirect compensation arrangements, as defined in § 411.354(c)(2), if all of the following conditions are satisfied:

(1) The compensation received by the referring physician (or immediate family member) described in § 411.354(c)(2)(ii) is fair market value for services and items actually provided and not determined in any manner that takes into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS.

(2) The compensation arrangement described in § 411.354(c)(2)(ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a bona fide employment relationship between an employer and an employee, in which case the arrangement need not be set out in a written contract, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.

(3) The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

As discussed below, Defendants cannot satisfy the requirements of this exception.

**a. The exception does not apply to direct compensation arrangements.**

As an initial matter, the “indirect compensation arrangement” exception applies only to indirect compensation arrangements, and has no application to direct compensation arrangements.

As discussed above, however, Drs. Vaccaro and Saleh do not merely have an indirect compensation arrangement with BRMC, but also have a direct compensation arrangement. *See* pages 21-25,

*supra*. Accordingly, Defendants cannot rely on the indirect compensation arrangement exception to escape liability under the Stark statute.

**b. There is no compliant written agreement.**

To qualify for the exception, the compensation arrangement must be “set out in writing, signed by the parties, and specif[y] the services covered by the arrangement.” As discussed below, however, there is no such written agreement covering many aspects of the relationship between BRMC and V&S.

**i. There is no written sublease of the Philips camera to BRMC.**

As discussed above, there is no written agreement between BRMC and V&S under which BRMC agrees to sublease the Philips camera from V&S, or setting forth the terms of any such sublease. *See* pages 45-46, *supra*. Nor is there any written agreement under which BRMC agrees to reimburse V&S for its payments to Philips under the Philips lease. Accordingly, the payments to V&S for the Philips camera cannot be protected by the indirect compensation arrangement exception.

**ii. The Equipment Sublease does not accurately describe the arrangement between the parties as to the GE camera.**

The Equipment Sublease purports to set forth the terms of the sublease of the GE camera. However, as BRMC acknowledges, the written agreement does not accurately describe the actual arrangement between the parties. The written document states that “[s]ubsequent to the execution of this Sublease, the Equipment will be moved to the Sublessee [i.e., BRMC].” Equipment Sublease, p. 4 (Apx., Doc. 12). This was not a trivial point. In his deposition, George Leonhardt discussed why it was disadvantageous to the hospital to have the equipment remain at V&S’s office:

From the hospital’s point of view, we were not interested in operating the camera on the site of their practice if we were leasing it. . . . If we were going to be involved in the operation of a nuclear camera, we wanted it to be in a location that would be attractive for any number of physicians on the medical staff to refer patients to. We didn’t believe

that any other physicians would want to have their patients have diagnostic work done at Vaccaro and Saleh's office whether the hospital was the ultimate provider of that service or not.

Leonhardt Dep., p. 40 (Apx., Doc. 1).

Nevertheless, despite these clear concerns, and even though the written document required the camera to be moved to the hospital, the GE camera was never moved to BRMC, but remained at V&S's office. In his deposition, George Leonhardt acknowledged that the written agreement did not accurately describe the parties' actual arrangement. Leonhardt Dep., p. 92 ("Q. So this agreement does not accurately describe the state of affairs in the four or five-month period after the agreement was executed; correct? A. That's correct.") (Apx., Doc. 1). Because the Equipment Sublease does not describe the actual arrangement between the parties, it cannot satisfy the requirement that the "arrangement" be set forth in a written agreement.

**iii. There is no written agreement obligating BRMC to reimburse V&S for the buyout of the GE lease, while allowing V&S to keep possession and ownership of the GE camera.**

In the Equipment Sublease, BRMC agreed to sublease the GE camera for a period of five years, during which period BRMC would have exclusive possession and use of the camera. Notwithstanding this agreement, BRMC in fact subsequently agreed to finance V&S's \$200,000 buyout of the GE lease. Philips paid the buyout fee to GE, and V&S signed a promissory note agreeing to repay Philips in 60 monthly installments of \$3,958.13. BRMC guaranteed V&S's obligation to Philips. Although not required by the guaranty agreement, BRMC has actually reimbursed V&S for its monthly buyout payments to Philips – indeed, BRMC continues to make such reimbursement payments to this day.

Nothing in the Equipment Sublease obligated BRMC to provide financing to V&S for an early buyout of the GE lease – particularly since BRMC was not obtaining possession or ownership of the camera as a result of the lease buyout. Nor is there any other signed agreement between



BRMC and V&S dealing with this matter. Accordingly, BRMC's payments to V&S in connection with the GE buyout cannot be protected by the indirect compensation arrangement exception.

**iv. There is no signed agreement on the terms of the space rental, the billing fee, and ancillary charges.**

As discussed above, for several months after the execution of the Equipment Sublease, BRMC paid V&S \$2,500 per month as "space rental" to leave the GE camera in V&S's office. In addition, BRMC paid \$1,000 a month for secretarial support, as well as other ancillary charges. BRMC also paid V&S a 10% billing fee for all collections resulting from tests performed on the nuclear camera.

Notably, however, there is no written agreement signed by the parties setting forth the terms of the space rental or other charges. On October 2, 2003, V&S sent BRMC a one-page letter purporting to summarize "the monthly charges for the nuclear facility while located at V&S Medical Associates." However, this letter does not purport to be an agreement, but is simply a unilateral statement from V&S. Moreover, this letter is not "signed by the parties," since it is not signed by BRMC. In addition, the letter does not purport to describe the terms of the parties' arrangement. How much space is being leased by BRMC? It doesn't say.<sup>17</sup> How long is the term of the space rental? It doesn't say.<sup>18</sup> Exactly what services is V&S going to provide in return for the 10% billing fee? It doesn't say. In short, even if this letter had been signed by BRMC, it would not satisfy the requirement that "[t]he compensation arrangement [be] set out in writing, signed by the parties, and specif[y] the services covered by the arrangement."

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<sup>17</sup> Notably, in order to satisfy the "space rental" exception, the arrangement must be set forth in a writing and "specif[y] the premises it covers." 42 C.F.R. § 411.357(a)(1).

<sup>18</sup> Notably, in order to satisfy the "space rental" exception, the lease must be for a term of at least one year. 42 C.F.R. § 411.357(a)(2).

c. **The compensation was determined in a manner that takes into account the value or volume of referrals or other business generated by Drs. Vaccaro and Saleh.**

The exception requires that the compensation “not [be] determined in any manner that takes into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS.” 42 C.F.R. § 411.357(p)(1). As discussed above, however, the compensation paid by BRMC manifestly was determined in a manner that took into account the value or volume of referrals or other business generated by Drs. Vaccaro and Saleh for BRMC. *See* pages 27-34, *supra*. Therefore, Defendants cannot satisfy the requirements of the indirect compensation arrangement exception.

d. **The compensation is not fair market value for items and services actually provided.**

The exception requires that the compensation be “fair market value for items and services actually provided.” 42 C.F.R. § 411.357(p)(1). The term “fair market value” is defined as follows:

Fair market value means the value in arm’s-length transactions, consistent with the general market value. “General market value” means the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals. With respect to rentals and leases described in § 411.357(a), (b), and (l) (as to equipment leases only), “fair market value” means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee. For purposes of this definition, a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.

42 C.F.R. § 411.351.

Thus, compensation is not fair market value if it is “determined in any manner that takes into account the volume or value of anticipated or actual referrals.” As discussed above, the compensation paid to V&S under the sublease arrangement was manifestly determined in a manner that took into account the volume and value of anticipated referrals. Accordingly, such compensation does not constitute fair market value.

**e. The arrangement violates the Anti-Kickback Statute.**

In order to satisfy the exception, “[t]he compensation arrangement [must] not violate the anti-kickback statute.” As discussed below, the arrangement between BRMC and Drs. Vaccaro and Saleh does in fact violate the Anti-Kickback Statute. Accordingly, Defendants cannot rely on the exception.

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For all the reasons discussed above, Defendants cannot satisfy any of the exceptions under the Stark statute and regulations. Accordingly, V&S is prohibited from making referrals to BRMC for designated health services, BRMC is prohibited from submitting claims to Medicare based on such referrals, and Medicare is prohibited from making payment on such claims. Therefore, Relator is entitled to summary judgment establishing that all claims based on such referrals constitute false claims.

**D. BRMC has submitted thousands of claims for designated health services based on prohibited referrals.**

In relevant part, the Stark regulations define “referral” to include either (i) “the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service for which payment may be made under Medicare Part B,” or (ii) “a request by a physician that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service.” 42 C.F.R. § 411.351. Thus, a physician who orders an outpatient test or procedure that is payable under Medicare Part B constitutes a referring physician. Similarly, a physician who admits a patient for inpatient services payable under Medicare Part A, or assumes responsibility for establishing the patient’s plan of care, constitutes a referring physician.

Historically, when a hospital such as BRMC submits a claim to Medicare, it does so using form UB-92.<sup>19</sup> BRMC 30(b)(6) Dep., p. 12-17 (Apx., Doc. 2). These claim forms are submitted electronically by BRMC. *Id.*, p. 12-13, 26. In box 82 of the UB-92 form, the hospital identifies the “attending” physician.<sup>20</sup> As BRMC stated in its discovery responses:

For inpatient services, the instruction Line 82 on the UB-92/HCFR 1450 form identifies “the clinician primarily responsible for the care of the patient from the beginning of the hospital episode. For SNF services, i.e., swing bed, the attending physician is the practitioner who certifies the SNF plan of care. For Outpatient and other Part B services, Line 82 on the UB-92/HCFR 1450 form identifies the physician that requested the surgery, therapy, diagnostic tests, or other services.” ... These instructions are

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<sup>19</sup> The UB-92 form has recently been replaced by the UB-04 form. Hospitals could begin using the UB-04 form on March 1, 2007, and were required to use that form by May 23, 2007. *See* <http://www.cms.hhs.gov/MLNMArticles/downloads/MM5072.pdf>. In its interrogatory responses, BRMC indicated that it began using the UB-04 form on March 1, 2007.

<sup>20</sup> In box 83, the hospital identifies “other” physicians, although this box is not relevant for the present motion.

consistent with instructions received from BRMC's Medicare intermediary, which instructions are followed when BRMC submits claims using the UB-92/HCFA 1450 forms.

Responses to Relators' Second Set of Interrogatories to Bradford Regional Medical Center, No. 4 (Apx., Doc. 44); *see also* BRMC's 30(b)(6) Dep., p. 18, 20 (Apx., Doc. 2) (acknowledging that, on Box 82, the "Attending" physician is the same as the admitting physician or, for outpatient claims, the ordering physician). It is clear, therefore, that the "attending" physician identified in box 82 makes a referral for purposes of the Stark statute. *See United States v. Rogan*, 459 F. Supp. 2d 692, 713 (N.D. Ill. 2006) ("The 'attending/operating' physician identified in Boxes 82 and 83 of Form UB-92 qualifies as a referring physician as that term is defined by the Stark Statute."), *affirmed*, 517 F.3d 449 (7<sup>th</sup> Cir. 2008).

In furtherance of a subpoena issued by Relators, the Court ordered CMS to produce the following:

A list of inpatient and outpatient Medicare claims submitted by Bradford Regional Medical Center ... to Highmark Medical Services, including the amount paid by Medicare on all such claims, on which either Peter Vaccaro, UPIN F84602, or Kamran Saleh, UPIN F90399, is identified as attending physician, referring physician, or other physician, for the time period October 1, 2003 to the present.

Order, filed September 5, 2007, Docket No. 92. In response, CMS produced two spreadsheets – one a list of inpatient claims, and the other a list of outpatient claims. In response to discovery requests, BRMC admitted that each line item on these spreadsheets identified an inpatient or outpatient hospital claim submitted by BRMC to Medicare and the amount paid to BRMC by Medicare for such claim.<sup>21</sup> Responses to Relators' Second Request for Admissions to Bradford Regional Medical

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<sup>21</sup> Inpatient and outpatient hospital services are "designated health services" under the Stark statute. 42 C.F.R. § 411.351.

Center, Request No. 1 (Apx., Doc. 45).<sup>22</sup> BRMC also admitted that, for all entries dated prior to March 1, 2007, the column “ATTEND” identified the physician listed by BRMC in Box 82 of the UB-92 claim form. *Id.*<sup>23</sup> Accordingly, it is undisputed that BRMC has submitted numerous claims for designated health services based on referrals from Drs. Vaccaro and Saleh.<sup>24</sup>

**E. The measure of damages is the amount paid on the false claims.**

Because BRMC has a “financial relationship” with Drs. Vaccaro and Saleh that is not subject to any exception, the doctors are prohibited from making referrals to the hospital for designated health services, and BRMC is precluded from submitting claims to Medicare based on such referrals. “In addition to prohibiting the hospital from submitting claims under these circumstances, the Stark Statute also prohibits payment by the Medicare program of such claims: ‘No payment may be made under this subchapter for a designated health service which is provided

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<sup>22</sup> These spreadsheets produced by CMS were attached as Exhibits A and B to Relators’ Second Request for Admissions to BRMC, and were provided to BRMC in paper and electronic form. Relators have included printouts of illustrative pages from these spreadsheets as Documents 46-47 in the accompanying Appendix. These printouts have been redacted to remove potentially identifying information. Because the documents run to several hundred pages in length, and cannot be conveniently examined in paper or .pdf form, Relators have submitted under seal a CD containing electronic versions of the unredacted spreadsheets.

<sup>23</sup> BRMC noted that, as of March 1, 2007, it has utilized the new UB-04 claims form, which has different numbering. Responses to Relators’ Third Set of Interrogatories to Bradford Regional Medical Center, Response No. 1 (Apx., Doc. 48). However, an attending physician is a referring physician, whether identified in form UB-92 or form UB-04. *See* CMS Manual System, Transmittal 1104, November 3, 2006, Pub 100-04 Medicare Claims Processing (<http://www.cms.hhs.gov/Transmittals/Downloads/R1104CP.pdf>) (“The attending provider [on line 76 of UB-04 form] is the individual who has overall responsibility for the patient’s medical care and treatment reported in this claim/encounter”).

<sup>24</sup> Given the number of claims at issue, and in an effort to keep the present motion manageable, Relators believe that it would be more appropriate for the parties to address the issue of the exact number of false claims, and the total amount of damages, in a separate round of briefing after the Court has ruled on the issue of liability.

in violation of subsection (a)(1) of this section.’ 42 U.S.C. § 1395nn(g)(1).” *United States v. Rogan*, 459 F. Supp. 2d 692, 712 (D. Ill. 2006), *affirmed*, 517 F.3d 449 (7<sup>th</sup> Cir. 2008).

Because the government would have paid nothing for the prohibited claims if it had known the true set of facts, the measure of damages is the amount of payments made by Medicare. *Rogan*, *supra*, 459 F. Supp. 2d at 727. In addition to treble damages, the False Claims Act imposes a mandatory civil penalty of between \$5,500 and \$11,000 for each false claim. Each submission of a false claim for payment is a separate violation of the statute, resulting in a mandatory penalty. *Rogan*, *supra* at 720; *see also United States v. Bornstein*, 423 U.S. 303, 313, 96 S. Ct. 523, 46 L. Ed. 2d 514 (1976); *United States v. Killough*, 848 F.2d 1523, 1533 (11th Cir. 1988). Accordingly, the Court should impose a mandatory civil penalty of \$5,500 to \$11,000 for each of these claims.

#### IV. RELATORS ARE ENTITLED TO SUMMARY JUDGMENT ON THEIR CLAIMS THAT DEFENDANTS VIOLATED THE ANTI-KICKBACK STATUTE

Because a knowing violation of the Stark statute constitutes a violation of the False Claims Act, it is not necessary to find that the arrangement among the Defendants also violated the Anti-Kickback Statute in order to impose liability under the FCA. However, as discussed below, the undisputed evidence clearly establishes that such arrangement does, in fact, violate the Anti-Kickback Statute.

**A. The payments to V&S were clearly intended to induce referrals.**

The Anti-Kickback Statute makes it illegal to knowingly pay or receive remuneration for referrals of services covered by a federal health care program. *See* 42 U.S.C. § 1320a-7b(b)(1)-(2). As the Third Circuit and other courts have recognized, the statute is violated if one purpose of the remuneration is to induce such referrals. *See United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985) (“If the payments were intended to induce the physician to use Cardio-Med’s services, the statute was violated, even if the payments were also intended to compensate for professional services.”); *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); 66 Fed. Reg. 856, 918 (“If any *one* purpose of remuneration is to induce or reward referrals of Federal health care program business, the statute is violated.”).

In the present case, the undisputed evidence clearly establishes that one of the purposes of the payments by BRMC to V&S was to induce or reward referrals. Indeed, George Leonhardt acknowledged that the purpose of the sublease arrangement was not simply to obtain a piece of equipment:

Q. Well, Mr. Leonhardt, that is a fairly cumbersome way to go out and acquire a piece of equipment, wouldn’t you agree?

A. Yes, if that was the only thing that we were trying to accomplish. Obviously, it wasn’t the only thing that we were trying to accomplish.

BRMC 30(b)(6) Dep., p.140 (Apx., Doc. 2). Leonhardt acknowledged that he hoped and expected to receive substantial referrals from V&S as a result of the sublease arrangement. *Id.*, p. 146, 156; Leonhardt Dep., p. 52, 57 (Apx., Docs. 2, 1). And as discussed above, he had substantial basis for expecting such referrals, since V&S’s own attorney assured BRMC that “[m]y clients have indicated that all of their Nuclear Medicine Studies can be accommodated by a combination of their current camera and those at BRMC.” Leonhardt Dep., p. 37 and Exhibit 2 (at V&S 01629) (Apx., Docs. 1, 40).



The fact that the payments to V&S were intended to induce referrals is also demonstrated by the fair market value analysis performed for BRMC prior to execution of the Equipment Sublease. This report expressly stated that the purpose of the “noncompete” payments was to “protect” certain “revenue streams,” and that BRMC’s revenue projections were based on the assumption that V&S would refer business to the hospital after execution of the sublease. Leonhardt Dep., p. 57 and Exhibit 4, p.14, 17 (Apx., Docs. 1, 7). As Defendants acknowledged, the only revenue streams that were adversely affected by V&S’s acquisition of the nuclear camera were V&S’s referrals for nuclear imaging tests, although BRMC feared losing other referral business from V&S. Saleh Dep., p. 37; Leonhardt Dep., p. 14, 57-58 and Exhibit 4 (at HOSP0007444); BRMC Dep., p. 160-62 and Exhibit 14 (at HOSP0007444) (Apx., Docs. 3, 1, 2, 7). Leonhardt projected that, if the parties entered into the sublease arrangement, BRMC would receive \$402,000 in profit from the additional nuclear imaging referrals expected to be made by V&S – more than the “pass-through” and “noncompete” payments under the Equipment Sublease. Leonhardt Dep., p. 71-72 and Exhibit 5 (Apx., Docs. 1, 8). In addition, BRMC would “protect” its existing referrals from V&S.

Not only did Leonhardt project such substantial referrals, but he acknowledged that he would not have entered into the lease arrangement without such referrals. Leonhardt Dep., p. 53 (Apx., Doc. 1). In other words, the anticipated referrals were a *sine qua non* of the entire arrangement. It is thus clear that a primary purpose of the payments under the sublease arrangement was to induce V&S to refer additional business to BRMC, as well as to continue its existing referrals.

Moreover, after the execution of the sublease, BRMC took steps to ensure that it in fact received the benefit of the anticipated referrals from V&S. Although the sublease required that the camera be moved to the hospital, BRMC agreed to pay V&S extra to keep the camera in its own office. Moreover, BRMC agreed to pay V&S a 10% billing fee for all tests performed on that

camera. Since Drs. Vaccaro and Saleh would naturally prefer to perform tests on a camera in their office, and would be paid a billing fee for all such tests, this arrangement ensured that BRMC would be the beneficiary of any tests ordered by V&S.

Finally, V&S was well aware that BRMC's purpose was to obtain their referrals. Indeed, their attorney directly accused BRMC of using the dispute over privileging as a means of extorting referrals, stating that "[t]he Medical Center is conditioning privileges on referrals streams. This is precisely the type of arrangement that the anti-kickback laws were intended to prevent." Saleh Dep., Ex. 5, at V&S00125 (Apx., Doc. 19). V&S's attorney bluntly stated that "[w]e know of no case that more clearly establishes a hospital's attempt to extract an exclusive referral stream from a physician." Leonhardt Dep., p. 21-22, 76-77 and Ex. 6 (Apx., Docs. 20, 1).

Because a primary purpose of the payments to V&S was to induce or reward referrals, the arrangement violates the Anti-Kickback Statute unless it meets the requirements of a safe harbor. And as discussed below, Defendants cannot meet such requirements.

**B. There is no applicable safe harbor.**

The Department of Health and Human Services has promulgated a number of safe harbors, compliance with which will protect a person from liability under the Anti-Kickback Statute. 42 C.F.R. § 1001.952. "In order for a business arrangement to comply with one of the exemptions set forth [in the regulations], each provision of that exemption must be met." 54 Fed. Reg. 3088.

The only safe harbor Defendants have identified as being potentially applicable is the safe harbor for equipment rentals set forth in 42 C.F.R. § 1001.952(c). This provision states as follows:

(c) Equipment rental. As used in section 1128B of the Act, "remuneration" does not include any payment made by a lessee of equipment to the lessor of the equipment for the use of the equipment, as long as all of the following six standards are met --

(1) The lease agreement is set out in writing and signed by the parties.

(2) The lease covers all of the equipment leased between the parties for the term of the lease and specifies the equipment covered by the lease.

(3) If the lease is intended to provide the lessee with use of the equipment for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such interval.

(4) The term of the lease is for not less than one year.

(5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or all other Federal health care programs.

(6) The aggregate equipment rental does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental. Note that for purposes of paragraph (c) of this section, the term fair market value means that the value of the equipment when obtained from a manufacturer or professional distributor, but shall not be adjusted to reflect the additional value one party (either the prospective lessee or lessor) would attribute to the equipment as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.

42 C.F.R. § 1001.952(c).

The requirements of the safe harbor are substantially identical to those of the “equipment rental” exception under the Stark statute. As discussed above, Defendants cannot meet the requirements of the Stark equipment rental exception. *See supra*, p. 35-45. For the same reasons, they cannot meet the requirements of the Anti-Kickback Statute safe harbor.

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Because a primary purpose of the payments to V&S was to induce or reward referrals, and because Defendants do not satisfy any safe harbor, Relators are entitled to summary judgment establishing that the arrangement between the parties violates the Anti-Kickback Statute.

**V. DEFENDANTS ACTED “KNOWINGLY” FOR PURPOSES OF THE FCA.**

Although the False Claims Act requires that a defendant act “knowingly,” it defines that term to mean that the defendant either “(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.” 31 U.S.C. § 3729(b); *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 241 (3d Cir. 2004). Thus, it is not necessary that the defendant have actual knowledge that a claim is false, or intend to defraud the government; it is sufficient if the defendant acts in deliberate ignorance or reckless disregard of the claim’s falsity.

The Supreme Court has noted that “[p]rotection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law.” *Heckler v. Cmty. Health Servs. of Crawford County, Inc.*, 467 U.S. 51, 63, 81 L. Ed. 2d 42, 104 S. Ct. 2218 (1984). “As Justice Holmes put it, ‘[m]en must turn square corners when they deal with the Government.’” *United States v. Rogan*, 517 F.3d 449, 452 (7th Cir. Ill. 2008), *quoting Rock Island, Arkansas & Louisiana R.R. v. United States*, 254 U.S. 141, 143 (1920). Thus, “[p]articipants in the Medicare program have a duty to familiarize themselves with the legal requirements for payment.” *United States v. Mackby*, 261 F.3d 821, 828 (9th Cir. 2001), *citing Heckler, supra*, 467 U.S. at 64 (“As a participant in the Medicare program, respondent had a duty to familiarize itself with the legal requirements for cost reimbursement”).

In the present case, the record clearly establishes that Defendants were well aware that their relationship raised issues under the Stark and Anti-Kickback Statutes, and that any venture needed to comply with such statutes. Indeed, as discussed above, this topic was the subject of letters and discussions between the parties. *See* pages 4-8, *supra*. Not only were the parties aware of the need

to comply with the Stark and Anti-Kickback statutes, but V&S repeatedly took the position that BRMC's actions violated such statutes, and were a clear attempt to obtain V&S's referrals. On January 22, 2002, attorney Marc Raspanti sent a letter to George Leonhardt, stating that the hospital's actions "violate federal law, in particular, the federal anti-kickback criminal statute." Saleh Dep., Ex. 5, at V&S00124 (Apx., Doc. 19). This letter also noted that the Stark statute and the False Claims Act provide civil penalties "for those who enter into arrangements which compensate based upon referrals." *Id.*, at V&S00125. The letter asserted that "The Medical Center is conditioning privileges on referrals streams. This is precisely the type of arrangement that the anti-kickback laws were intended to prevent." *Id.*

On February 15, 2002, Mr. Raspanti sent another letter to Mr. Leonhardt, noting that "the anti-kickback laws are violated even where only 'one purpose' of a payment or exchange is to induce referrals." Saleh Dep., Ex. 7, at V&S00155; Leonhardt Dep., p. 76-77 and Ex. 6 (Apx., Doc. 20). Mr. Raspanti stated that "We know of no case that more clearly establishes a hospital's attempt to extract an exclusive referral stream from a physician." *Id.*; Leonhardt Dep., p. 21-22, 76-77 and Ex. 6 (Apx., Docs. 20, 1). Shortly before the parties agreed to the sublease arrangement, on January 17, 2003, Mr. Raspanti accused BRMC of engaging in "economic blackmail," and asked for "[a]ll opinions concerning the legality of the nuclear camera venture" contemplated by BRMC. Saleh Dep., Ex. 15, at V&S 00560, 00561 (Apx., Doc. 26).

The parties were clearly aware that any arrangement between them presented significant risk of violating the Stark and Anti-Kickback Statutes. *See* Vaccaro Dep., p. 41 ("we were always worried about violating Stark or an anti-kickback"). Indeed, V&S's attorney expressly stated that "we would want to be sure that we will get an unconditional opinion or an advisory opinion from the Office of the Inspector General, to the effect that the final arrangement and the process that led to it would not be deemed inappropriate." Saleh Dep., Ex. 16, at V&S 01642;

Kabala Dep., Ex. 3 (Apx., Doc. 27). All parties acknowledged that it was essential to obtain an OIG advisory opinion before entering into any under arrangements venture. BRMC 30(b)(6) Dep., p. 138; *see also* Saleh Dep., p. 101. (Apx., Doc. 2, 3). However, when the parties decided to enter into the sublease arrangement, they neither asked for nor received an advisory opinion from OIG. BRMC 30(b)(6) Dep., p. 191 (Apx., Doc. 2).

Perhaps most damningly, although all of the Defendants were represented by attorneys throughout the entire process, they do not claim that their attorneys told them the arrangement complied with the Stark and Anti-Kickback Statutes. Indeed, as this Court is well aware, Defendants have conspicuously refused to assert that they relied on the advice of their counsel, which would have required waiver of the attorney-client privilege and allowed Relators to discover exactly what counsel said about the arrangement. *See* Saleh Dep., p. 92 (acknowledging that he is not contending that he relied on the advice of his counsel about the legality of the arrangement); Vaccaro Dep., p. 42 (agreeing that “you are not saying, ‘I thought this was okay, because my attorneys told me this was okay’”); BRMC Dep., p. 214 (admitting that BRMC was not relying on advice of counsel) (Apx., Doc. 3, 4, 2). One can be sure, however, that if their attorneys had given Defendants an opinion that the arrangement complied with the statutes, Defendants would have waived the privilege in a heartbeat.<sup>25</sup>

In short, Defendants were well aware that any venture between them might be seen as violating the Stark and Anti-Kickback Statutes. One of the parties had repeatedly accused the other of illegally seeking to extort referrals in violation of such statutes. All parties had recognized the necessity of obtaining an OIG advisory opinion before entering into an arrangement. Nevertheless, not only did the parties not obtain such an advisory opinion, but they did not even obtain an opinion

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<sup>25</sup> Indeed, if counsel had provided such assurance, it would approach malpractice to continue as attorneys for Defendants, rather than appearing as witnesses.

from their own attorneys that the arrangement was in compliance with the statutes. Under the circumstances of this case, there is simply no way to describe such failure as anything other than, at a minimum, “deliberate ignorance” or “reckless disregard.” Accordingly, Defendants acted “knowingly” for purposes of the False Claims Act.

### **CONCLUSION**

For the above reasons, summary judgment should be granted in favor of the United States and against Defendants under the False Claims Act.

This 10<sup>th</sup> day of September, 2008.

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Certificate of Service

I hereby certify that on September 10, 2008, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will automatically send email notification of such filing to the following attorneys of record:

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This 10<sup>th</sup> day of September, 2008.

Respectfully submitted,

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